U.S. Department of Agriculture Program Solicitation

Small Business Innovation Research Program Fiscal Year 2002

Phase I Closing Date: August 30, 2001 Phase II Closing Date: February 7, 2002

| CONTENTS Page | | | | |
|---------------|-----------------------------|--|----|--|
| 1.0 | General Program Description | | | |
| | 1.1 | Introduction | | |
| | 1.2 | Three-phase Program | | |
| | 1.3 | Follow-on Funding | | |
| | 1.4 | Eligibility and Limitations | | |
| 2.0 | Definit | tions | 4 | |
| | 2.1 | Research or Research and Development | 4 | |
| | 2.2 | Small Business Concern | 4 | |
| | 2.3 | Principal Investigator | 5 | |
| | 2.4 | Socially and Economically Disadvantaged Small Business Concern | 5 | |
| | 2.5 | Women-owned Small Business Concern | 6 | |
| | 2.6 | United States | | |
| | 2.7 | Program Solicitation | 6 | |
| | 2.8 | Subcontract | 6 | |
| | 2.9 | Funding Agreement | 6 | |
| | 2.10 | Commercialization | 6 | |
| 3.0 | Propos | sal Preparation Instructions and Requirements | 6 | |
| | 3.1 | Proposal Requirements | 6 | |
| | 3.2 | General Content | 7 | |
| | 3.3 | Proposal Format | 8 | |
| 4.0 | Metho | d of Selection and Evaluation Criteria | 13 | |
| | 4.1 | Introduction | | |
| | 4.2 | Initial Screening Criteria | 14 | |
| | 4.3 | Phase I Evaluation Criteria | 14 | |
| | 4.4 | Phase I Review Process | 15 | |
| | 4.5 | Phase II Evaluation Criteria | 16 | |
| | 4.6 | Phase II Review Process | 17 | |
| | 4.7 | Notice to Proposers | 17 | |
| 5.0 | Consid | lerations | 17 | |
| | 5.1 | Awards | 17 | |
| | 5.2 | Reports | 18 | |
| | 5.3 | Payment Schedules | 18 | |
| | 5.4 | Proprietary Information | 18 | |
| | 5.5 | Rights in Technical Data | 19 | |
| | 5.6 | Copyrights | 19 | |
| | 5.7 | Patents and Inventions | 20 | |
| | 5.8 | Research Involving Special Considerations | 20 | |
| | 5.9 | Grantee Commitments | | |
| | 5.10 | Additional Information | 21 | |
| | 5 11 | Certifications | 22 | |

| 6.0 | Submission of Proposals | | |
|------|-------------------------------------|---|--|
| | 6.1 | Deadlines for Proposals | |
| | 6.2 | Number of Copies | |
| | 6.3 | Address | |
| | 6.4 | Acknowledgment of Proposals | |
| | 6.5 | Bindings | |
| | 6.6 | Packaging | |
| | 6.7 | Questions Pertaining to the USDA SBIR Program or to this Solicitation | |
| | 6.8 | Requests for Additional Copies of this Solicitation | |
| | 6.9 | Information on Proposal Status | |
| 7.0 | Scien | tific and Technical Information Sources | |
| 8.0 | Resea | rch Topic Descriptions | |
| | 8.1 | Forests and Related Resources | |
| | 8.2 | Plant Production and Protection | |
| | 8.3 | Animal Production and Protection | |
| | 8.4 | Air, Water, and Soils | |
| | 8.5 | Food Science and Nutrition | |
| | 8.6 | Rural and Community Development 3' | |
| | 8.7 | Aquaculture | |
| | 8.8 | Industrial Applications | |
| | 8.9 | Marketing and Trade | |
| 9.0 | Submission Forms and Certifications | | |
| | | Proposal Cover Sheet (CSREES-667) | |
| | | Project Summary (CSREES-668) | |
| | | Budget (CSREES-2004) | |
| | | Assurance Statement(s) (CSREES-2008) | |
| | | National Environmental Policy Act Exclusions Form (CSREES-2006) | |
| 10 0 | Samn | le Pronosal | |

Please note that the text of the proposal should be prepared using no smaller than 11 point font size regardless of whether it is single or double spaced.

USDA'S PROGRAM SOLICITATION SMALL BUSINESS INNOVATION RESEARCH FISCAL YEAR 2002

1.0 GENERAL PROGRAM DESCRIPTION

1.1 Introduction

The U.S. Department of Agriculture (USDA) invites science-based small business firms to submit research proposals under this program solicitation entitled "Small Business Innovation Research Program, Fiscal Year 2002." Firms with strong scientific research capabilities in any of the topic areas described in section 8.0 are encouraged to participate. USDA will support high-quality research or research and development (R&D) proposals containing advanced concepts related to important scientific problems and opportunities that could lead to significant public benefit if the research is successful.

Objectives of the Small Business Innovation Research (SBIR) program include stimulating technological innovation in the private sector, strengthening the role of small businesses in meeting Federal research and development needs, increasing private sector commercialization of innovations derived from USDA-supported research and development efforts, and fostering and encouraging participation by women-owned and socially and economically disadvantaged small business firms in technological innovation. Questions of a general nature about this SBIR solicitation should be directed to:

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Cooperative State Research, Education, and Extension Service
U.S. Department of Agriculture
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1.2 Three-phase Program

NOTE: **This program solicitation is primarily for the preparation and submission of phase I proposals.** However, the solicitation is also applicable for those preparing phase II proposals, for it contains the necessary forms for proposal submission, delineates the evaluation criteria that will be used, and provides other relevant information. More detailed guidance on phase II proposal preparation will be provided by the Director, SBIR Program, in a letter that is sent out in the Fall of each year to phase I awardees.

This program solicitation is issued pursuant to the Small Business Innovation Development Act of 1982, Pub. L. No. 97-219, as amended (15 U.S.C. 638) and Section 630 of the Act making appropriations for Agriculture, Rural Development, and Related Agencies' programs for fiscal year ending September 30, 1987, and for other purposes, as made applicable by Section 101(a) of Pub. L. No. 99-591, 100 Stat. 3341. This program is administered by the Cooperative State Research, Education, and Extension Service (CSREES) of the USDA.

This program is subject to the provisions found at 7 CFR Part 3403. These provisions set forth procedures to be followed when submitting grant proposals, rules governing the evaluation of proposals and the awarding of grants, and regulations relating to the post-award administration of grant projects.

The program will be carried out in three separate phases. Phase I is to determine the scientific or technical feasibility of ideas submitted by proposers on research topic areas described in section 8.0 of this solicitation with each award ranging up to \$80,000 for a period normally not to exceed 6 months. The phase I proposal should concentrate on research which will significantly contribute to **proving the scientific or technical feasibility** of the approach or concept and which would be a prerequisite to further USDA support in phase II.

Phase II awards will be made during fiscal year (FY) 2002 to firms with approaches that appear sufficiently promising as a result of phase I studies with each award ranging up to \$300,000 for a period normally not to exceed 24 months. Only those small businesses previously receiving phase I awards in either FYs 2000 or 2001 are eligible to submit phase II proposals in FY 2002. Please note, however, that for each phase I project funded the awardee may apply for a phase II award only once. Proposals for phase II may only be submitted to the Federal agency from which the phase I award was received.

Phase I awardees in FY 2001 who are unable to submit phase II proposals for valid reasons during the FY 2002 funding cycle, will be eligible to apply for phase II support no later than the FY 2003 funding cycle. One reason for not submitting the phase II proposal during the FY 2002 funding cycle would be one which precludes completion of the phase I project within the designated award period. In such instances, the awardee must request in writing, prior to the end of the phase I grant period, a no-cost extension from the Authorized Departmental Officer, outlining the circumstances which prevent completion of the project. Once the no-cost extension request is approved, any remaining Federal funds may be expended on the project in accordance with the approved budget within the extended award period.

Phase II is the principal research or research and development effort and will require a more comprehensive application, outlining the proposed effort in detail. At the appropriate time, the Director of the SBIR Program will send a letter to all eligible phase I awardees requesting phase II proposals. The letter will provide instructions for preparing phase II proposals and a deadline date (normally early February of each year) for submitting applications. USDA recognizes that phase II awards may not be sufficient in either dollars or time for the firm to complete the total research and development required to bring the project results to commercialization in the market place. Therefore, completion of the research under these circumstances may necessarily have to be carried into phase III, the commercialization phase.

See subsection 5.1 for estimated number of FY 2002 phase I and phase II awards and their established dollar limit.

The purpose of phase III is to stimulate technological innovation and the national return on investment from research through the pursuit of commercialization objectives resulting from the USDA-supported work carried out in phases I and II. No Federal SBIR funds may be used to support phase III projects. However, firms are strongly encouraged to secure phase III funding from their own resources or from other public and private sources of funds. Additionally, phase III is to be conducted by the small business concern (including joint ventures and limited partnerships).

1.3 Follow-on Funding

In addition to supporting scientific research and development, another important goal of this program is to provide incentive and opportunity for small firms to convert USDA-sponsored research to technological innovation in the private sector. All proposed research should have some potential commercial outcome, and applicants are encouraged to obtain a contingent commitment for non-SBIR follow-on funding to pursue further development of the commercial potential during phase III. Government funding pays for research relating to Federal objectives (phases I and II); non-SBIR (public or private) funding pays for development of commercial objectives (phase III).

Obtaining follow-on financial commitment(s) is the responsibility of the proposer. USDA understands that any such commitment will likely be contingent upon the awardee attaining technical objectives that are mutually agreed upon between the small business and the provider of the follow-on funding. These objectives should be closely related to those delineated in the phase II research proposal. The technical objectives should be clearly defined and measurable, and should be specified in the commitment agreement at the threshold level that would justify such an investment. The objectives do not have to be identical to those stated in the phase II proposal, but they must be able to be accomplished within the scope of the proposed SBIR-funded research. Any letters or other forms of tentative commitment for follow-on phase III funding from sources other than Federal SBIR Programs, will be considered.

Phase I proposals should contain a brief description of any potential commercial application(s) and whether or not the small business will attempt to secure follow-on, non-SBIR funding to pursue the commercial development of the expected products from the proposed research. In order for phase II proposers to receive consideration of follow-on funding during the review and evaluation process, a signed contingent commitment between the small business and the entity providing the follow-on financial support should be submitted with the phase II application. While such commitment agreements are optional when submitting phase II proposals, they will receive special consideration as a point of merit in the review and evaluation process where proposals are evaluated as being of approximately equal technical merit. The maximum value (in phase II evaluation) will be given for a signed formal agreement with reasonable terms and funding equal to or in excess of the Federal investment requested in the phase II proposal. The agreement should set forth the specific amount of phase III funds and should indicate the dates that such funds will be made available to the small business. Also, the agreement should contain a few specific technical objectives which, if achieved in phase II, will make the commitment usable by the small business. The terms cannot be contingent upon the obtaining of a patent, due to the length of time this process requires.

The commitment may be in the form of venture capital or a package including venture capital, contract research and development, a joint venture, a research and development limited partnership, or other agreement with a non-SBIR source of funding. No amortization, repayment, or repurchase of commitment funds may be included during the phase II period of performance.

Follow-on funding commitments will not be counted as part of the 50-page limit for phase II proposals.

1.4 Eligibility and Limitations

Each organization submitting a proposal must qualify as a small business concern for research or research and development purposes (see definitions in section 2.0).

A joint venture or a limited partnership is eligible to submit a proposal provided that the entity created qualifies as a small business concern in accordance with section 2 of the Small Business Act, 15 U.S.C. 632, and the definition found at subsection 2.2 of this solicitation. A joint venture must provide documentation confirming that it can act as a single legal entity for purposes of a grant awarded under the SBIR program.

2.0 DEFINITIONS

The following definitions apply for purposes of this solicitation:

2.1 Research or Research and Development

Research or research and development (R&D) means any activity which is:

- (A) A systematic, intensive study directed toward greater knowledge or understanding of the subject studied;
- **(B)** A systematic study directed specifically toward applying new knowledge to meet a recognized need; or
- **(C)** A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

2.2 Small Business Concern

A small business concern means a concern which **at the time of award** of phase I and phase II funding agreements meets the following criteria:

- (A) Is organized for profit, independently owned or operated, is not dominant in the field in which it is proposing, has its principal place of business located in the United States, has a number of employees not exceeding 500 (full-time, part-time, temporary, or other) in all affiliated concerns owned or controlled by a single parent concern, and meets the other regulatory requirements outlined in 13 CFR Part 121. Business concerns, other than licensed investment companies or State development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661 et seq., are affiliates of one another when directly or indirectly (l) one concern controls or has the power to control the other; or (2) third parties (or party) control or have the power to control both. Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR 121.103. The term "number of employees" is defined in 13 CFR 121.106. Business concerns include, but are not limited to, any individual, partnership, corporation, joint venture, association, or cooperative.
- **(B)** Is at least 51 percent owned or, in the case of a publicly owned business, at least 51 percent of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens.
- **(C)** Is the primary source of employment of the principal investigator of the proposed effort **at the time of award** and during the conduct of the proposed research. Primary employment means that more than one-half of the principal investigator's time is spent in the employ of the small

business. Primary employment with the small business applicant precludes full-time employment with another organization. This requirement applies to both phase I and phase II awards. If the proposed principal investigator is employed by another organization (e.g., university or another company) at the time of submission of the application, documentation must be submitted with the proposal from the principal investigator's current employer verifying that, in the event of an SBIR award, he/she will become a less than half-time employee of such organization and will remain so for the duration of the SBIR project. While the principal investigator must work more than one-half of his/her time for the small business during the entire grant period, there is no minimal time requirement for what percentage of the principal investigator's time is spent working on the proposed research.

(D) Is the primary performer of the proposed research effort. A minimum of **two-thirds** of the research or analytical work, as determined by budget expenditures, must be performed by the proposing organization under **phase I grants**. For **phase II awards**, a minimum of **one-half** of the research or analytical effort must be conducted by the proposing firm. For both phase I and phase II the research must be performed in the United States. **The space used by the SBIR awardee to conduct the research must be space over which it has exclusive control for the period of the grant.**

2.3 Principal Investigator

The individual designated by the applicant to be principally responsible for the scientific or technical direction of the work described in a proposal. Therefore, the individual should have a scientific/technical background.

2.4 Socially and Economically Disadvantaged Small Business Concern

A socially and economically disadvantaged small business concern is one:

- (A) Which is at least 51 percent owned by (i) an Indian tribe or a native Hawaiian organization, or (ii) one or more socially and economically disadvantaged individuals; and
- **(B)** Whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

For purposes of this solicitation, a socially and economically disadvantaged individual is defined as a member of any of the following groups: Black Americans, Hispanic Americans, Native Americans, Asian-Pacific Americans, Subcontinent Asian Americans, other groups designated from time to time by the Small Business Administration (SBA) to be socially disadvantaged, or any other individual found to be socially and economically disadvantaged by the SBA pursuant to section 8(a) of the Small Business Act, 15 U.S.C. 637(a).

Note: The certification of socially and economically disadvantaged small business at item 2 of Form CSREES-667 is for statistical purposes only.

2.5 Women-owned Small Business Concern

Women-owned small business concern means a small business concern that is at least 51 percent owned by a woman or women who also control and operate it. "Control" as used in this context means exercising the power to make policy decisions. "Operate" as used in this context means being actively involved in the day-to-day management of the concern.

Note: Certification of women-owned small business at item 3 of Form CSREES-667 is for statistical purposes only.

2.6 United States

United States means the 50 States, the territories and possessions of the United States, the Commonwealth of Puerto Rico, Guam, American Samoa, the Commonwealth of the Northern Marianas, the Virgin Islands of the United States, and the District of Columbia.

2.7 Program Solicitation

A program solicitation is a formal request for proposals whereby an agency notifies the small business community of its research or R&D needs and interests in selected areas and invites proposals from small business concerns in response to these needs and interests.

2.8 Subcontract

A subcontract is any agreement, other than one involving an employer-employee relationship, entered into by a Federal Government funding agreement awardee for supplies or services required solely for the performance of the original funding agreement.

2.9 Funding Agreement

A funding agreement is any contract, grant, or cooperative agreement entered into between any Federal agency and any small business for the performance of experimental, developmental or research work funded in whole or in part by the Federal Government.

2.10 Commercialization

Commercialization is defined as the process of developing markets and producing and delivering products or services for sale (whether by the originating party or by others); as used here, commercialization includes both government and commercial markets.

3.0 PROPOSAL PREPARATION INSTRUCTIONS AND REQUIREMENTS

3.1 Proposal Requirements

This is a solicitation for **phase I research proposals on advanced concepts** from small businesses which have strong research capabilities in the basic and applied sciences.

The proposed research must be responsive to one of the USDA program interests stated in the research topic descriptions of this solicitation. The USDA does not prioritize between research topics or between different research objectives within a specific research topic. Thus, the specific research

objectives proposed by applicants are investigator-initiated and not initiated by the USDA, and applicants are free to propose any research project that fits within one of the nine research topics listed in section 8.0. The same research can often be the basis for technological innovation, new commercial products, processes, or services which benefit the public. This is a desirable economic objective, and such proposals are encouraged.

Proposals must cover only scientific research activities. A small business must not propose technical assistance, demonstration projects, classified research, or patent applications. Many of the research projects supported by the SBIR program lead to the development of new products based upon the research results obtained during the project. However, projects that seek funding solely for product development where no research is involved, i.e., the funds are needed to permit the development of a product based on previously completed research, will not be accepted.

Literature surveys and appropriate discussions should be included in the research proposal but should not be proposed as a part of the SBIR phase I or phase II effort. Proposals that deal principally with developing proven concepts for commercial markets or scaling up previously developed prototypes for commercial production should not be submitted, since such efforts are considered the responsibility of the private sector and therefore are not supported by USDA. A proposal must be limited to only one topic, the title of which must be entered on the Proposal Cover Sheet, Form CSREES-667, of the application. The same proposal may not be submitted under more than one topic. However, an organization may submit separate proposals on different topics or different proposals on the same topic under this solicitation. Where similar research is discussed under more than one topic, the proposer should choose that topic whose description appears most relevant to the proposer's research concept. Proposers may respond to any of the topics listed under section 8.0. Research may be carried out through the construction and evaluation of a laboratory prototype, where necessary. Duplicate proposals will be returned to the applicant without review.

The purpose of a research proposal is to provide a written statement that contains sufficient information to persuade members of the research community who review the proposal and then advise the USDA SBIR professional staff that the proposed research is a sound approach to an important scientific question and is worthy of support under the stated USDA evaluation criteria (see section 4.0). The proposal should be self-contained and written with the care and thoroughness accorded papers for publication. Each proposal should be reviewed carefully by the applicant and by others knowledgeable on the subject to ensure inclusion of data essential for comprehensive evaluation.

3.2 General Content

This solicitation is designed to reduce the investment of time and cost to small business concerns in preparing formal proposals. Those who wish to respond should submit a research proposal of **no more than 25 pages**, including cover page, project summary page, budget pages, and all proposal-related enclosures or attachments unless otherwise stated. The following items do not count as part of the 25-page limit for phase I or 50-page limit for phase II: 1) Table of Contents (see subsection 3.3(C)); 2) Response to Previous Review (see subsection 3.3(D)); 3) Assurance Statement(s) (see subsection 3.3(O)); 4) National Environmental Policy Act Exclusions Form (see subsection 3.3(P)); 5) letters from consultants, subcontractors or cooperative research and development agreement (CRADA) cooperators (see subsection 3.3(H)); **vitae for these individuals, however, are part of the page limit**; 6) letter from a university describing the arrangement if university facilities are being used (see subsection 3.3(G)); 7) follow-on funding agreements for phase II proposals (see subsection 1.3); 8) documentation

of multiple Phase II awards to be submitted with phase I proposals if the applicant has received more than 15 phase II awards during the preceding five fiscal years (see subsection 3.3(M)).

The text must be prepared on only one side of the page using standard size (8 ½" x 11"; 21.6 cm x 27.9 cm) white paper, with margins not less than one inch on all sides and **no type smaller than 11 point font size regardless of whether it is single or double spaced.** In the interest of equity to all proposers, no additional attachments, appendixes, or references beyond the 25-page limitation will be considered in the proposal evaluation process, and proposals in excess of the 25-page limitation will not be considered for review or award. In addition, supplementary materials, revisions, and/or substitutions **will not be accepted after the due date for proposals**. Phase II applicants should submit a research proposal of no more than 50 pages, including cover page, budget, and all proposal-related enclosures or attachments unless otherwise stated.

It is not necessary to provide a lengthy discourse on commercial applications in the phase I proposal except to discuss them briefly under subsection 3.3(E), as appropriate, as well as under subsection 3.3(J). The phase I proposal must be principally directed at feasibility-related research or R&D on the specific topic chosen.

3.3 Proposal Format

- (A) Proposal Cover Sheet Photocopy and complete Form CSREES-667 and use it as page l of the proposal. All pages must be consecutively numbered. The original of the Proposal Cover Sheet must contain the pen-and-ink signatures of the proposed principal investigator and the authorized organizational official. A proposal which does not contain the required signatures may be returned to the proposing small business without review. All other copies of the proposal must also contain a proposal cover sheet but facsimile or photocopied signatures will be accepted. The title should be a brief (80-character maximum), clear, specific designation of the research proposed. It will be used to provide information to Congress and also will be used in issuing press releases; it should not contain highly technical words. In addition, phrases such as "investigation of" or "research on" should not be used.
- **(B) Project Summary** Photocopy and complete Form CSREES-668 and use it as page 2 of the proposal. The technical abstract should include a brief description of the problem or opportunity, project objectives, and a description of the effort. Anticipated results and potential commercial applications of the proposed research also should be summarized in the space provided. Key words, to be provided in the last block on the page, should characterize the most important aspects of the project.

The information contained on Form CSREES-668, "Project Summary," of successful proposals will be published by USDA and, therefore, should not contain proprietary information.

- **(C) Table of Contents** A Table of Contents, itself unpaginated, should be placed immediately following the Project Summary, Form CSREES-668. This table should direct the reviewer to the pages for all sections of the proposal, beginning with the Proposal Cover Sheet.
- **(D) Resubmitted Proposals** If you are submitting a proposal in which the project described was previously submitted to the SBIR program but not funded, state the proposal is a resubmission on Question 10 of the Proposal Cover Sheet, Form CSREES-667. The revised proposal should clearly indicate the changes that have been made in the project. A clear statement acknowledging

comments of the previous review, indicating revisions, rebuttals, etc., is part of the evaluation criteria as noted in subsection 4.3(F). Proposals that are resubmissions **must** respond to the previous submission's panel summary on no more than one page, titled "RESPONSE TO PREVIOUS REVIEW," which is to be placed directly after the Table of Contents. This section will not be counted within the page limitations of the proposal. (Refer to subsection 4.2 (I) Initial Screening Criteria.)

- **(E) Technical Content** Begin the main body of the proposal on page 3 and include:
 - (1) **Identification and Significance of the Problem or Opportunity** Clearly state the specific technical problem or opportunity addressed and its importance.
 - (2) **Background and Rationale** Indicate the overall background and technical approach to the problem or opportunity and the part that the proposed research plays in providing needed results
 - (3) Relationship with Future Research or Research and Development Discuss the significance of the phase I effort in providing a foundation for the phase II R&D effort. State the anticipated results of the approach if the project is successful (phases I and II). This should address: (a) the technical, economic, social, and other benefits to the Nation and to users of the results such as the commercial sector, the Federal Government, or other researchers; (b) the estimated total cost of the approach relative to benefits; and, if appropriate, (c) any specific policy issues or decisions which might be affected by the results.
 - **(4) Phase I Technical Objectives** State the specific objectives of the research or research and development effort, including the technical questions it will try to answer to determine the feasibility of the proposed approach.
 - (5) Phase I Work Plan This work plan must provide an explicit, detailed description of the research or research and development approach. The plan should list the tasks to be performed, provide details of the methodology that would be used to research each task, including statistical analysis, if applicable, and indicate how and where the work will be carried out. The phase I effort should attempt to determine the technical feasibility of the proposed concept. The work plan should be linked with the technical objectives of the research and the questions the effort is designed to answer. This section should constitute a substantial portion of the total proposal.
 - (6) Related Research or Research and Development Describe significant research or R&D activities from relevant literature that are directly related to the proposed effort, including any conducted by the principal investigator or by the proposing small business, how the proposed effort expands on the related work, and any planned coordination with outside sources. The proposer must persuade reviewers that he or she is aware of related research in the selected subject. It is critical that the applicant make a convincing case that the proposed research builds upon previous research and, if successful, will lead to the development of new technology or a substantial improvement of existing technology.
 - (7) **References** Provide a complete list of all references cited in the proposal. For each reference, provide the complete name for each author, the date of the publication, the full title of the article, name of the journal or book published and the page numbers. The references should be listed in alphabetical order using the last name of the first author.

- (F) Key Personnel and Bibliography Identify key personnel (including consultants and subcontractors and any other person receiving compensation under the grant) involved in the effort and include information on their directly related education and experience. For each key person, provide a chronological list of the most recent representative publications in the topic area during the preceding five years, including those in press. List the authors (in the same order as they appear on the paper), the full title, and the complete reference as these usually appear in journals. Where vitae are extensive, efforts should be made to reduce them to one page by focusing on only the most relevant experience or publications in order to meet the proposal size limitation in phase I and phase II.
- (G) Facilities and Equipment Describe the types, location, and availability of instrumentation and physical facilities necessary to carry out the work proposed. Items of equipment to be purchased must be fully justified under this section. When purchasing equipment or a product under the SBIR funding agreement, the small business should purchase only American-made items whenever possible. If university facilities are being used, there must be a letter in the proposal from the authorized organizational representative of the university describing the arrangement and testifying that the facilities will be subject to the exclusive use and control of the applicant. These letters will not be considered a part of the 25-page limitation for phase I proposals or the 50-page limitation for phase II proposals.
- (H) Outside Services Involvement of university or other outside personnel in the planning and research stages of the project as consultants or through subcontracting arrangements is permitted and may be particularly helpful to small firms that have not previously received Federal research awards. Establishment of a CRADA with a USDA Agricultural Research Service laboratory or other Federal laboratory may also be beneficial to proposing firms. If the proposal involves outside consultants, subcontracts or involvement with a CRADA partner, these arrangements should be described in detail. Proposals must include letters from proposed consultants, subcontractors or CRADA cooperators indicating their willingness to serve in order for such participation to be considered during the proposal review and evaluation process (see subsection 4.3(C) or 4.5(D), as appropriate). These letters will not be considered a part of the 25-page limitation for phase I proposals or the 50-page limitation for phase II proposals.
- (I) Satisfying the Public Interest Specify how the proposed research will satisfy one or more of the following objectives: (1) Develops sustainable agricultural production systems; (2) Protects natural resources and the environment; (3) Creates a safe, nutritious and affordable food supply; (4) Develops value-added food and non-food products from agricultural materials; (5) Enhances global competitiveness; and (6) Enhances economic opportunity and quality of life, especially for people in rural areas.
- (J) Potential Post Application Briefly describe the commercialization potential of the proposed research in phase I. In phase II commercialization potential is more important; therefore, this section should be more extensive in a phase II proposal. In addition, indicate whether there appears to be a potential use of the proposed research by the Federal Government. Include a brief description of the proposing company (e.g., date founded, number of employees) and its field of interest. What are the major competitive products in this field, and what advantages will the proposed research have over existing technology (in application, performance, technique, efficiency or cost).

- **(K) Current and Pending Support** If a proposal, substantially the same as the one submitted in response to this solicitation, has been previously funded or is currently funded, pending, or about to be submitted to another Federal agency or to USDA in a separate action, the proposer must provide the following information:
 - (1) Name and address of the agency(s) to which a proposal was submitted, or will be submitted, or from which an award is expected or has been received.
 - (2) Date of actual or anticipated proposal submission or date of award, as appropriate.
 - (3) Title of proposal or award, identifying number assigned by the agency involved, and the date of program solicitation under which the proposal was submitted or the award was received.
 - **(4)** Applicable research topic area for each proposal submitted or award received.
 - **(5)** Title of research project.
 - **(6)** Name and title of principal investigator for each proposal submitted or award received.

USDA will not make awards that duplicate research funded (or to be funded) by other Federal agencies.

- **(L) Budget** Photocopy and complete Form CSREES-2004 only for the **phase under which you are currently applying**. (An applicant for phase I funding should not submit both phase I and phase II budgets.) Please note the following in completing the budget: It will be necessary to include supporting detail for each budget category. Please provide details (with costs) of all salaries and wages (including hourly wage, etc.), nonexpendable equipment, supplies, travel, subcontracts, and "All Other Direct Costs" for which support is requested on a separate sheet of paper and place immediately behind Form CSREES-2004. Subcontracts must be indicated on a separate Form CSREES-2004. The budget form and the page providing supporting budget justification will be considered a part of the 25-page limitation for phase I proposals or the 50-page limitation for phase II proposals.
 - (1) Salaries and Wages Indicate the number and kind of personnel for whom salary support is sought, including job tasks. For key personnel, also indicate the number of work months of involvement to be supported with USDA funds (see section labeled "CSREES Funded Work Months"), and explain how the level of compensation was established, e.g., the hourly rate of pay, the monthly rate of pay, or the yearly rate of pay.
 - (2) Equipment Performing organizations are expected to have appropriate facilities, suitably furnished and equipped. However, funding for items of equipment may be requested provided that they are specifically identified with the dollar amount and adequately justified (see item (E) of this section), but such requests should normally not exceed 10% of the budget for phase I. This limit does not apply to phase II budgets. Equipment is defined as an article of nonexpendable, tangible personal property having a useful life of more than 1 year and an acquisition cost of \$5000 or more per unit. However, consistent with recipient policy, lower limits may be established. Vesting of title to equipment purchased with funds provided under an SBIR funding agreement will be determined by USDA. Awardees should plan to lease expensive equipment. The inclusion of equipment will be carefully reviewed with respect to need and appropriateness for the research proposed.

- (3) Travel The type and extent of travel and its relationship to the project should be specified. Funds may be requested for field work or for travel to professional meetings. Phase I requests for foreign travel are discouraged but may be approved (e.g., proposals submitted to the Marketing and Trade topic area that are focused on export issues) based on the justification provided in the proposal. The inclusion of foreign travel in phase II will be carefully reviewed with respect to need and appropriateness for the research proposed. In the budget narrative, for both domestic and foreign travel, provide the purpose, the destination, method of travel, number of persons traveling, number of days, and estimated cost for each trip. If details of each trip are not known at the time of proposal submission, provide the basis for determining the amount requested.
- (4) All Other Direct Costs Other anticipated direct costs not included above should be itemized. Examples include, but are not limited to, subcontracts and consultants. Subcontracting, as defined in subsection 2.8, and consulting services may not exceed one-third of the research or analytical effort during phase I and one-half of the research or analytical effort during phase II, as determined by budget expenditures. In addition, subcontractors must perform their portion of the work in the United States. A budget and budget narrative stating subcontractual costs and the rationale for the amount of consulting costs is required. Note: For proposals involving subcontractual or consulting arrangements, the applicant must submit an agreement or letter of consent signed by the subcontractor or consultant in order for such participation to be evaluated during the proposal review process (see subsection 4.3(C) or 4.5(D), as appropriate). These letters will not be considered a part of the 25-page limitation for phase I proposals or the 50-page limitation for phase II proposals.
- (5) Fee A reasonable fee, not to exceed 7%, is permitted under this program solicitation but proposers are encouraged to minimize fee requests due to the small amount of funds available. All fees are subject to negotiation with USDA. If a fee is requested, the amount should be indicated in block M., "Other," on the budget sheet.
- (6) Indirect Costs If available, the current rate negotiated with the cognizant Federal negotiating agency should be used. Indirect costs may not exceed the negotiated rate. If a negotiated rate is used, the percentage and base should be indicated in the space allotted under item K. on the budget sheet. If no rate has been negotiated, a reasonable dollar amount in lieu of indirect costs may be requested, which will be subject to approval by USDA. In the latter case, if a proposal is recommended for funding, an indirect cost rate proposal must be submitted to support the amount of indirect costs requested. CSREES will request an indirect cost rate proposal and provide instructions, as necessary. A proposer may elect not to charge indirect costs and, instead, use all grant funds for direct costs. If indirect costs are not charged, the phrase "None requested" should be written in this space.
- (7) **Cost Sharing** Cost sharing is permitted for proposals under this program solicitation; however, cost sharing is not required nor will it be an evaluation factor in considering the competitive merit of proposals submitted.

(M) Documentation of Multiple Phase II Awards

(1) A small business concern that submits a proposal for a funding agreement for phase I of an SBIR Program and that has received more than 15 phase II SBIR awards during the preceding 5 FYs must document the extent to which it was able to secure third phase funding to develop

concepts resulting from previous second phase SBIR awards. In addition, the documentation must include the name of the awarding agency, date of award, funding agreement number, amount, topic or subtopic title, follow-on agreement amount, source and date of commitment and current commercialization status for each phase II. (This information will not be counted toward the 25-page limitation.); and

- (2) USDA shall collect and retain the information submitted under subparagraph (M)(1) at least until the General Accounting Office submits the report required under section 105 of the Small Business Research and Development Enhancement Act of 1992.
- (N) Certifications Regarding Non-Delinquency on any Federal Debt, Drug-free Workplace, Debarment and Suspension, and Lobbying Certifications are accomplished by signing Form CSREES-667, Proposal Cover Sheet. (For instructions see subsection 5.11(A) through (D).)
- **(O) Assurance Statement(s)** See subsection 5.8. Photocopy and complete Form CSREES-2008. This form will not be considered a part of the 25-page limitation for phase I proposals or the 50-page limitation for phase II proposals.
- **(P)** National Environmental Policy Act Exclusions Form (NEPA) See subsection 5.11(E). Photocopy and complete Form CSREES-2006 and place it at the end of the proposal. This form will not be considered a part of the 25-page limitation for phase I proposals or the 50-page limitation for phase II proposals.

4.0 METHOD OF SELECTION AND EVALUATION CRITERIA

4.1 Introduction

Phase I and phase II proposals will be judged competitively in a two-stage process, based primarily upon scientific or technical merit. First, each proposal will be screened by USDA scientists to ensure that it is responsive to stated requirements contained in this solicitation (see subsection 4.2). Proposals found to be responsive will be technically evaluated by peer scientists knowledgeable in the appropriate scientific field using the criteria listed in subsection 4.3 or subsection 4.5, as appropriate. Each proposal will be judged on its own merits. Unsolicited proposals or proposals not responding to research topic areas outlined in section 8.0 of this program solicitation are not eligible to be considered for a phase I SBIR award and, hence, will be returned to the proposing firm without review.

External peer reviewers will be used during the technical evaluation stage of this process.Selections will be made from among recognized specialists who are uniquely qualified by training and experience in their respective fields to render expert advice on the merit of proposals received. It is anticipated that these experts will be drawn from universities, Government, and non-profit research organizations. If possible, USDA intends that peer review groups shall be balanced with minority and female representation and with an equitable age distribution.

Final decisions will be made by USDA based upon the ratings assigned by reviewers and consideration of other factors, **including the potential commercial application**, possible duplication of other research, any critical USDA requirements, program balance, budget limitations and, for phase II proposals only, any follow-on funding commitment. There is no commitment by USDA to fund any particular proposal, to support any specific number of proposals in a given research topic area, or to

make a specific number of awards under either phase I or phase II. USDA also may elect to fund several or none of the proposed approaches to the same topic. Care will be taken to avoid actual and potential conflicts of interest among reviewers. Evaluations will be confidential to USDA staff members, peer reviewers, and the proposed principal investigator(s), to the extent permitted by law.

4.2 Initial Screening Criteria

To avoid misunderstanding, applicants should be aware that **proposals not satisfying all of the screening criteria may be returned to the proposing entity without review. Returned proposals may not be resubmitted** (with or without revision) **under this solicitation.** The initial screening criteria are the following:

- (A) The proposing firm must qualify as a small business concern as defined in subsection 2.2.
- **(B)** The proposal must meet the General Content requirements as described in subsection 3.2.
- **(C)** Proposals must be limited to one topic (see subsection 3.1).
- **(D)** The proposed budget must be within the budget limit identified in subsection 5.1.
- **(E)** The proposed duration of phase I projects should normally not exceed 6 months, except in special, justified circumstances, and the duration of phase II projects should normally not exceed 24 months. Where a proposed research project requires more than 6 months to complete in phase I, a longer grant period, not to exceed 18 months, may be considered. A proposer of a phase I project with an anticipated duration beyond 6 months should specify and justify the length of duration in the proposal at the time of its submission to USDA in order for it to be considered.
- **(F)** Proposals must cover scientific research activities only (see subsection 3.1).
- **(G)** The proposed phase I research must fall within a solicited topic area. (See section 8.0 for the listing of research topic descriptions.)
- (H) A proposal must contain adequate scientific/technical information to state clearly the research plan and objectives. USDA reserves the right not to submit for review any proposal which it finds to have insufficient scientific/technical information.
- (I) A proposal must address concerns of the previous review panel. USDA reserves the right not to submit for review any proposal found not to be responsive to the previous review.

4.3 Phase I Evaluation Criteria

USDA plans to select for award those proposals offering the best value to the Nation. The primary evaluation criteria used by reviewers are listed below. Approximately equal consideration will be given to each criterion, **except for item (A) which will receive twice the value of any of the other items:**

(A) Scientific and Technical Feasibility: Is there a thorough background section with an up-to-date literature review? Are the stated objectives logical and will they lead toward proving the technical feasibility of the approach or concept? Does the research plan offer an original and innovative approach to the problem and sufficient detail to indicate how each research objective

will be investigated? Can the research plan reasonably be completed in the requested grant period?

- **(B) Importance of the Problem:** Does the proposal provide sufficient justification for the importance of the problem and clearly indicate the anticipated commercial potential of the proposed research? Is the proposed project in the public interest by satisfying one or more of the technical objectives listed in subsection 3.3.?
- (C) Investigator and Resource Qualifications: Is adequate bibliographic information provided to document that the principal investigator, other key staff, and any consultants have the appropriate training and experience to carry out the proposed research plan? Is it clear that the principal investigator will work a minimum of 51 percent of his/her time for the small business during the period of the grant and that the small business will conduct a minimum of two-thirds of the research effort? If consultants, subcontractors or CRADA cooperators are involved in the project are letters from these individuals included in the proposal verifying their willingness to participate in the research study? Are adequate research facilities available that the small business either owns or controls for the duration of the grant? Is adequate instrumentation available for the proposed research plan?
- **(D) Budget:** Is the budget appropriate for the proposed research plan? Is sufficient budget detail provided to indicate clearly how the funds would be utilized?
- **(E) Duplication:** Does the proposed research substantially duplicate any ongoing or previous research by the small business or by other researchers? Does the proposal clearly indicate how the proposed technology would differ significantly from existing technology? If the small business or a consultant has received or applied for patent(s) pertaining to the proposed technology, does the proposed research constitute a legitimate feasibility study?
- **(F) Resubmission:** If your proposal is a resubmission, have you responded to the feedback you received from the previous year's panel summary by modifying the proposal or providing rebuttal to points indicated in the panel summary? Have you included a "Response to Previous Review" to make it clear exactly which changes you have made. (Refer to subsection 3.3(D), Proposal Format.)

4.4 Phase I Review Process

USDA uses confidential peer review as the basis for evaluating all phase I proposals. There are 10 separate review panels corresponding to each of the topic areas listed in Section 8.0. (The Plant Production and Protection topic area is subdivided into Biology and Engineering review panels). All reviewers are drawn primarily from universities, government, and non-profit research organizations. For each topic area a leading research scientist is appointed as a topic manager. In consultation with the SBIR program staff, this individual appoints a review panel. The review panel meets in Washington, D.C., to evaluate all proposals. Proposals are reviewed both by members of the review panel and by ad hoc reviewers with specific expertise appropriate for each proposal. The panel discusses each proposal carefully and then ranks the proposals. The panel rankings determine which proposals are funded.

Considerable effort is made to ensure that the review process is confidential. All reviewers are instructed to handle all proposals in complete confidence. Under the reviewer's signature on the review

sheet the following sentence appears: "The reviewer whose signature appears above agrees to treat the contents of this proposal as confidential and that no basis for a conflict-of-interest has been found."

Every effort is made to avoid even the appearance of a conflict-of-interest (COI). The USDA has very detailed rules on COI that are followed during the review process. If a panel member has a COI on a proposal, he/she is excused from the panel meeting while the particular proposal is being discussed. USDA is committed to ensuring the review process is fair and is handled with confidence.

4.5 Phase II Evaluation Criteria

A phase II proposal may be submitted **only** by a USDA phase I awardee. The primary evaluation criteria used by reviewers are listed below and except for item (B) are largely identical to those for phase I. Approximately equal consideration will be given to each criterion, **except for items (A) and (B) which will receive twice the value of any of the other items:**

- (A) Scientific and Technical Feasibility: Is there a thorough background section with an up-to-date literature review? Are the stated objectives logical and appropriate for a two year research and development period? Does the research plan offer an original and innovative approach to the problem and sufficient detail to indicate how each research objective will be investigated?
- **(B) Degree to Which Phase I Objectives were Met and Technical Feasibility Established:** Are the phase I objectives clearly stated and phase I results presented in sufficient detail to permit a reviewer to determine whether the objectives were fully met and technical feasibility clearly established?
- **(C) Importance of the Problem:** Does the proposal provide sufficient justification for the importance of the problem and clearly indicate the anticipated commercial potential of the proposed research? Is the proposed project in the public interest by satisfying one or more of the technical objectives listed in subsection 3.3(I)?
- (D) Investigator and Resource Qualifications: Is adequate bibliographic information provided to document that the principal investigator, other key staff, and any consultants have the appropriate training and experience to carry out the proposed research plan? Is it clear that the principal investigator will work a minimum of 51 percent of his/her time for the small business during the period of the grant and that the small business will conduct a minimum of one-half of the research effort? If consultants, subcontractors or CRADA cooperators are involved in the project are letters from these individuals included in the proposal verifying their willingness to participate in the research study? Are adequate research facilities available that the small business either owns or controls for the duration of the grant? Is adequate instrumentation available for the proposed research plan?
- **(E) Budget:** Is the budget appropriate for the proposed research plan? Is sufficient budget detail provided to indicate clearly how the funds would be utilized?
- **(F) Duplication:** Does the proposed research substantially duplicate any ongoing or previous research by the small business or by other researchers? Does the proposal clearly indicate how the proposed technology would differ significantly from existing technology? If the small business or a consultant has received or applied for patent(s) pertaining to the proposed technology, does the proposed research constitute a legitimate feasibility study?

In the event that two or more proposals are of approximately equal merit, a follow-on funding commitment for continued development in phase III will be an important consideration. The value of any commitment will depend upon the degree of commitment made by non-Federal investors, with the maximum value resulting from a signed agreement with reasonable terms for an amount at least equal to the funding requested from USDA in phase II.

4.6 Phase II Review Process

USDA uses confidential peer review as the basis for evaluating all phase II proposals. All reviewers are drawn primarily from universities, government, and non-profit research organizations. However, there are far fewer proposals at phase II and a different process is used. There are no review panels. Instead, six to eight top experts for each proposal are contacted to secure their agreement to serve as an ad hoc reviewer. A proposal is not sent to a reviewer unless he/she agrees to review the proposal in strict confidence. In addition, under the reviewer's signature on the review sheet the following sentence appears: "The reviewer whose signature appears above agrees to treat the contents of this proposal as confidential and no basis for a conflict-of-interest has been found." The same COI rules used in the phase I are used for phase II and no individual is sent a proposal where even the appearance of a COI exists.

4.7 Notice to Proposers

Technical reviewers will base their conclusions and recommendations on information contained in the proposal. It cannot be assumed that reviewers are acquainted with any experiments referred to within a proposal, with key individuals, or with the small business itself.

After final decisions have been announced, a panel summary that briefly sets forth the main strengths and weaknesses of the proposal, plus written reviews of the proposal, will be sent to the proposed principal investigator(s). The reviews will not include the scores or the identities of the reviewers. Due to funding limitations and USDA's desire to support as many worthwhile projects as possible, it may be necessary for USDA to reduce the amount of an award below the amount requested by a small business (or to fund only certain objectives outlined in the proposal). Any significant changes will be discussed with the proposing firm, which may then be asked to submit a revised budget reflecting the reduced amount. In the event that this occurs, specific instructions will be provided to the proposer.

5.0 CONSIDERATIONS

5.1 Awards

USDA expects to make approximately 90 phase I awards ranging up to \$80,000 each to small businesses in FY 2002, depending upon the availability of funds. Awards are expected to be made on or before May 15, 2002. USDA will announce the names of those concerns receiving awards, and successful proposers will then normally have 6 months after awards are made to carry out their proposed phase I effort.

USDA expects to make approximately 35 phase II awards ranging up to \$300,000 each to previous USDA phase I awardees, depending upon the results of the phase I efforts, the scientific and technical merit of the phase II proposal, and the availability of funds.

In accordance with the guidelines contained in 31 U.S.C. 6301-6308, and the authority contained in Section 630 of the Act making appropriations for Agriculture, Rural Development, and Related

Agencies' programs for fiscal year ending September 30, 1987, and for other purposes, as made applicable by Section 101(a) of Public Law Number 99-591, 100 Stat. 3341, all phase I and phase II awards will be issued as research grants.

5.2 Reports

For both phase I and phase II an original and two copies of a brief interim progress report must be submitted at approximately the mid-point in the project. In addition, an original and two copies of a comprehensive final performance report must be submitted within 30 days following expiration of the Phase I grant and within 90 days following expiration of the Phase II grant. The report should include a single-page project summary as the first page. This summary should include the purpose of the research, a brief description of the research carried out, the research findings or results, and, in a final paragraph, potential applications (commercial or other) of the research. The balance of the report should include a comparison of actual accomplishments with the goals established for the grant; the reasons for slippage if established goals were not met; estimates of technical feasibility; and additional pertinent information such as an explanation of cost over-runs or unexpectedly high unit costs. Also, identify all other recipients (public and private) of the research results documented in the phase I or phase II report. This report should be submitted to Dr. Charles F. Cleland, Director, SBIR Program (see subsection 1.1 for address, telephone, and facsimile numbers).

A final "Financial Status Report" (SF-269) is due within 90 days after the expiration date of the grant and should be submitted to the Funds Management Branch, Office of Extramural Programs at the address listed below, in accordance with instructions contained in Section 3015.82 of the Uniform Federal Assistance Regulations.

Funds Management Branch
Office of Extramural Programs
Cooperative State Research, Education, and Extension Service
U.S. Department of Agriculture
STOP 2298
1400 Independence Avenue, S.W.
Washington, D.C. 20250-2298
Telephone: (202) 401-4527

5.3 Payment Schedules

Payments will be made to the recipient by electronic transfer. The frequency of payment as well as required forms and pertinent submission instructions for each project will be provided to the small business concern when the funding agreement is forwarded to it for acceptance.

5.4 Proprietary Information

If a proposal contains proprietary information that constitutes a trade secret, proprietary commercial or financial information, confidential personal information, or data affecting the national security, it will be treated in confidence to the extent permitted by law, provided the information is clearly marked by the proposer with the term "confidential proprietary information," is confined to a separate page or pages, and provided the following legend also appears in the designated area at the bottom of the proposal's cover sheet (Form CSREES-667):

The following pages (specify) contain proprietary information which (name of proposing organization) requests not be released to persons outside the Government, except for purposes of evaluation.

USDA, by law, is required to make the final decision as to whether the information is required to be kept in confidence. Information contained in unsuccessful proposals will remain the property of the proposer. However, USDA will retain for one year one file copy of all proposals received; extra copies will be destroyed. Public release of information for any proposal submitted will be subject to existing statutory and regulatory requirements. The legislation reauthorizing the SBIR Program strengthened the protection of awardee firms relative to maintaining confidentiality of proprietary information for a period of four years after the end of the grant period. However, any proposal which is funded will be considered an integral part of the award and normally will be made available to the public upon request through the Freedom of Information Act, except for designated proprietary information.

The inclusion of proprietary information is discouraged unless it is necessary for the proper evaluation of the proposal. If proprietary information is to be included, it should be limited, set apart from other text on a separate page, and keyed to the text by numbers. It should be confined to a few critical technical items which, if disclosed, could jeopardize the obtaining of foreign or domestic patents. Trade secrets, salaries, or other information which could jeopardize commercial competitiveness should be similarly keyed and presented on a separate page. Proposals or reports which attempt to restrict dissemination of large amounts of information may be found unacceptable by USDA. Any other legend than that listed in the first paragraph of this section may be unacceptable to USDA and may constitute grounds for return of the proposal without further consideration. Without assuming any liability for inadvertent disclosure, USDA will limit dissemination of such information to its employees and, where necessary for the evaluation of the proposal, to outside reviewers on a confidential basis. Since technical reports by the principal investigator(s) may be made available to the public, such reports shall not contain any restrictive language purporting to limit their use other than that which is set off on a proprietary page. However, USDA, to the extent permitted by law, normally will honor a request to delay release of the report for 6 months, or longer if reasonable, so the proposer may seek patent protection or follow-on-funding where appropriate.

5.5 Rights in Technical Data

Rights in technical data, including software developed under the terms of any funding agreement resulting from a proposal submitted in response to this solicitation, shall remain with the grantee. However, the Government shall have the limited right to use such data for Governmental purposes and shall not release such data outside the Government without permission of the grantee for a period of four years from completion of the project under which the data were generated. Effective at the conclusion of the four-year period, the Government shall retain a royalty-free license for Governmental use of any technical data delivered under the agreement, whether patented or not.

5.6 Copyrights

With prior written permission of the Authorized Departmental Officer, the grantee normally may copyright and publish (consistent with appropriate national security considerations, if any) material developed with USDA support. USDA receives a royalty-free license for the Federal Government and requires that each publication contain the following acknowledgment and disclaimer statement:

"This material is based upon work supported by the U.S. Department of Agriculture under Grant No. (awardee should enter agreement number here). Any opinions, findings, and conclusions or

recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of the U.S. Department of Agriculture."

The last sentence may be omitted from articles published in scientific journals.

5.7 Patents and Inventions

Allocation of rights to inventions shall be in accordance with 35 U.S.C. 202-206 and the Department of Commerce implementing regulations entitled "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts and Cooperative Agreements" (37 CFR Part 401). These regulations provide that small businesses normally may retain the principal worldwide patent rights to any invention developed with USDA support. USDA receives a royalty-free license for Federal Government use, reserves the right to require the patentee to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it domestically. To the extent authorized by 35 U.S.C. 205, USDA will not make public any information disclosing a USDA-supported invention for a four-year period to allow the grantee a reasonable time to file an initial patent application. Additional information may be obtained by contacting:

Mr. M. Howard Silverstein Deputy Assistant General Counsel for Patents U.S. Department of Agriculture STOP 1415 1400 Independence Avenue, S.W. Washington, D.C. 20250-1415

5.8 Research Involving Special Considerations

A number of situations frequently encountered in the conduct of scientific research require the submission of special information for a particular project. Since some types of research targeted for SBIR support have high probability of involving either recombinant deoxyribonucleic acid (DNA) molecules, human subjects at risk, or vertebrate animals, special instructions follow.

If the proposed research will involve either recombinant DNA molecules, human subjects at risk, or vertebrate animals, the proposal must so indicate by checking "Yes" in Item 9 of Form CSREES-667 and then completing Form CSREES-2008. Further, in the event that the project is funded, the proposer may be required to have the research plan reviewed and approved by the appropriate review board or committee. It is suggested that proposers contact local universities, colleges, or nonprofit research organizations which have established such reviewing mechanisms to have this service performed.

Guidelines to be applied and observed when conducting such research are outlined below.

- (A) Recombinant DNA Molecules The performing organization is required to comply with the guidelines established by the National Institutes of Health entitled, <u>Guidelines for Research Involving Recombinant DNA Molecules</u>. In the event a project involving recombinant DNA or RNA molecules results in a grant award, a qualified Institutional Biosafety Committee must approve the research before funds will be released.
- **(B) Human Subjects at Risk** Regulations issued by the Department of Agriculture to be used in safeguarding the rights and welfare of human subjects used in research supported with USDA grant funds are contained in 45 CFR Part 46, and USDA regulations set forth in 7 CFR part 1c. All nonexempt research projects involving human subjects must be approved by an Institutional Review Board prior to commencing actual substantive work.
- (C) Animal Care The performing organization must comply with the Animal Welfare Act (7 USC, 2131-2156); Public Law 89-544, 1996, and the regulations issued by the Department of Agriculture in 9 CFR parts 1, 2, 3, and 4. In the case of domesticated farm animals housed under farm conditions, the grantee must adhere to the principles stated in the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, Federation of Animal Sciences Societies, 1999. In the event a project involving the use of living vertebrate animals results in a grant award, funds will be released only after a qualified Institutional Animal Care and Use Committee has approved the project.

5.9 Grantee Commitments

Upon issuance of a research grant by USDA, the awardee will be required to make certain legal commitments through acceptance of the award document and the terms and conditions attached thereto, as well as any project-specific terms or conditions outlined. Most of these terms and conditions are contained in USDA's Uniform Federal Assistance Regulations, 7 CFR Part 3015, which will be incorporated into all phase I awards resulting from this program solicitation and will be mailed in the package of materials when the research grant is forwarded to the awardee for acceptance. These regulations primarily consolidate internal policies and procedures relating to USDA's assistance programs and implement various Federally issued assistance policies, including applicable Federal cost principles and uniform administrative requirements. Advance copies of these regulations are available upon request.

5.10 Additional Information

- (A) This program solicitation is intended for informational purposes and reflects current planning. If there is any inconsistency between the information contained herein and the terms of any resulting SBIR funding agreement, the terms of the funding agreement are controlling.
- (B) Before the award of an SBIR funding agreement, USDA requires the submission of certain organizational management, personnel, and financial information to assure responsibility of the proposer, including certification that the proposing organization is in compliance with the Civil Rights Act of 1964. Form CSREES-666 (both sides) should be completed to provide the necessary organizational information, and Form CSREES-665 should be used to certify compliance with Title VI of the Civil Rights Act of 1964. (If portions of the information requested on Form CSREES-666 are not applicable to the proposing organization or entity,

"N/A" should be written in the space provided.) These forms will be provided to the small business concern by the Office of Extramural Programs, CSREES, prior to the forwarding of the funding agreement for acceptance. The information contained in both forms must normally be submitted on a one-time basis only. (If sufficient changes occur within the organization to warrant submission of new or additional information, additional forms should be requested by calling (202) 401-5050.) It is anticipated that all phase I awardees will be required to submit the above information, but phase II awardees will be concerned primarily with submitting new forms only if they have undergone significant changes in organization, personnel, finance, or policies including those relating to civil rights. Phase II awardees will be asked to submit an updated statement of financial condition (such as the latest audit report, financial statement or balance sheet).

- **(C)** If a proposer or a grantee is contemplating any type of transaction involving the entity (i.e., merger, spin-off, or sale), it is advised that the proposer or the grantee contact the Director of the SBIR program for knowledge of how the transaction may affect a potential grant or the grant, as applicable.
- **(D)** USDA is not responsible for any monies expended by the proposer prior to the award of any funding agreement.
- **(E)** This program solicitation is not an offer by USDA and does not obligate USDA to make any specific number of awards. Also, awards under this program are contingent upon the availability of funds.
- (F) Unsolicited proposals will not be accepted under the SBIR program in either phase I or phase II

5.11 Certifications

- (A) <u>Instructions for Statement as to Delinquency on Federal Debts by Applicants for Federal Assistance</u> Pursuant to OMB Circular A-129, (implemented by USDA in 7 CFR Part 3), "Except where required by law or approved by the head of the agency, no award of Federal funds shall be made to an applicant who is delinquent on a Federal debt until the delinquent account is made current or satisfactory arrangements are made between affected agencies and the debtor." The certification of non-delinquency applies only to the organization requesting financial assistance and not to the individual Principal Investigator. By indicating "no" for item 8, Form CSREES-667, Proposal Cover Sheet, the applicant is providing the statement of non-delinquency on any Federal debt. For the purposes of this statement, the following definitions of delinquency apply:
 - (1) Direct loans a debt more than 31 days past due on a scheduled payment.
 - (2) Grants recipients of a "Notice of Grants Cost Disallowance" who have not repaid the disallowed amount or who have not resolved the disallowance.
 - (3) Guaranteed and insured loans recipients of a loan guaranteed by the Federal Government that the Federal Government has repurchased from a lender because the borrower breached the loan agreement and is in default.

Examples of debts include delinquent taxes, audit disallowances, guaranteed and direct student loans, housing loans, farm loans, business loans, Department of Education institutional loans, benefit overpayments and other miscellaneous administrative debts.

NOTE: An applicant answering "Yes" to this question on Form CSREES-667 must attach explanatory information detailing all relevant particulars concerning the Federal debt.

(B) <u>Certifications Regarding Drug-Free Workplace Requirements (Grants)</u> - These certifications are required by 7 CFR Part 3017, implementing the Drug-Free Workplace Act of 1988, 41 U.S.C. 701 et seq. Copies of the regulations may be obtained by contacting the Proposal Services Unit at (202) 401-5048, or via the Office of Extramural Programs web page at the following address: www.reeusda.gov/crgam/oep.

Certification Regarding Drug-Free Workplace Requirements, Alternative I, For Grantees Other Than Individuals

The grantee certifies that it will or will continue to provide a drug-free workplace by:

- (a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;
- (b) Establishing an ongoing drug-free awareness program to inform employees about --
- **(1)** The dangers of drug abuse in the workplace;
- (2) The grantee's policy of maintaining a drug-free workplace;
- (3) Any available drug counseling, rehabilitation, and employee assistance programs; and
- **(4)** The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;
- (c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);
- (d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will --
- (1) Abide by the terms of the statement; and
- (2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;
- (e) Notifying the agency in writing, within ten calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer on whose grant activity the convicted employee was working, unless the Federal agency

- has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;
- **(f)** Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted --
 - (1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 701 et seq.; or
 - (2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;
- (g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

Certification Regarding Drug-Free Workplace Requirements, Alternative II, For Grantees Who Are Individuals

- (a) The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant.
- **(b)** If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing, within 10 calendar days of the conviction, to the grant officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

Instructions for Certification of Drug-Free Workplace Requirements

- **1.** By signing Form CSREES-667, the grantee is providing the certification set forth above.
- 2. The certification is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.
- **3.** Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.
- **4.** Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all

vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios).

- **5.** If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph three).
- **6.** Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules:

<u>Controlled substance</u> means a controlled substance in Schedules I through V of the Controlled Substances Act (21 U.S.C. 812) and as further defined by regulation at 21 CFR 1308.11 through 1308.15;

<u>Conviction</u> means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

<u>Criminal drug statute</u> means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

<u>Employee</u> means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) all "direct charge" employees; (ii) all "indirect charge" employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplaces).

(C) <u>Debarment or Suspension Requirements</u> - Certification Regarding Debarment, Suspension, and Other Responsibility Matters - Primary Covered Transactions, and Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - Lower Tier Covered Transactions (Form AD-1048).

These certifications are required by the regulations implementing Executive Order 12549, Debarment and Suspension, 7 CFR Part 3017.510, Participants' responsibilities. Copies of the regulation may be obtained by contacting the Proposal Services Unit at (202) 401-5048, or via the Office of Extramural Programs web page at the following address: www.reeusda.gov/crgam/oep.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - Lower Tier Covered Transactions (Form AD-1048)

Form AD-1048 containing certification for each lower tier covered transaction will be sent to each phase I and phase II grantee at the time of award with the award letter. It should not be submitted to CSREES but should be maintained by the applicant with the other records relating to the award project.

Certification Regarding Debarment, Suspension, and Other Responsibility Matters - Primary Covered Transactions

- (1) The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:
 - (a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
 - (b) have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or Local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
- (c) are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or Local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and
- (d) have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or Local) terminated for cause or default.
- (2) Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Instructions on Certification Regarding Debarment And Suspension

- **1.** By signing Form CSREES-667, the prospective primary participant is providing the certification for primary covered transactions set forth above.
- 2. The inability of a person to provide the certification will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.
- **3.** The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.
- **4.** The prospective primary participant shall provide immediate written notice to the Authorized Departmental Officer in accordance with 7 CFR Part 3017.510(c) if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

- **5.** The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meaning set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549. You may contact CSREES for assistance in obtaining a copy of those regulations.
- **6.** The prospective primary participant agrees by certification that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.
- 7. The prospective primary participant further agrees by certification that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion Lower Tier Covered Transactions," from Form AD-1048, provided by the department or agency entering into this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
- **8.** A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant will require its prospective lower tier participants to provide immediately written notice to the proposer if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List. As used herein, lower tier covered transactions generally include:
 - **a.** Any transaction (other than a procurement contract) for goods and services, regardless of type;
 - **b.** Any procurement contract for goods and services, regardless of type, that is expected to equal or exceed the Federal cap on small purchases (currently, \$100,000); and
 - **c.** Any procurement contract for goods and services, regardless of amount, under which the recipient will have a critical influence on or substantive control over the covered transaction (i.e., principal investigators and providers of federally required audit services).
- **9.** Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
- **10.** Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

(D) Notice to Applicants - Certification/Disclosure Requirements Related to Lobbying - Section 319 of Public Law 101-121 (31 U.S.C. 1352), imposes prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans. Certain provisions of the law also apply to Federal commitments for loan guarantees and insurance; however, it provides exemptions for Indian tribes and tribal organizations.

Current and prospective recipients (and their subtier contractors and/or subgrantees) are prohibited from using Federal funds, other than profits from a Federal contract, for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement or loan. In addition, for each award action in excess of \$100,000 (or \$150,000 for loans) on or after December 23, 1989, the law requires recipients and their subtier contractors and/or subgrantees to: (1) certify that they have neither used nor will use any appropriated funds for payment to lobbyists, (2) disclose the name, address, payment details, and purpose of any agreements with lobbyists whom recipients or their subtier contractors or subgrantees will pay with profits or **nonappropriated** funds on or after December 23, 1989; and (3) file quarterly updates about the use of lobbyists if material changes occur in their use. The law establishes civil penalties for noncompliance.

USDA, CSREES regulations implementing Section 319 of Public Law 101-121 are at 7 CFR Part 3018. Copies of 7 CFR Part 3018 may be obtained by contacting the Proposal Services Unit at (202) 401-5048, or via the Office of Extramural Programs web page at the following address: http://www.reeusda.gov/crgam/oep.

Certification Regarding Lobbying - Contracts, Grants, Loans, and Cooperative Agreements - In signing Form CSREES-667, the applicant certifies, to the best of his or her knowledge and belief, that:

- 1. No Federal appropriated funds have been paid or will be paid, by or on behalf of the applicant, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal Loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan or cooperative agreement;
- 2. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a Federal contract, grant, loan, or cooperative agreement, the applicant shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions:
- **3.** The applicant shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to

file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

(E) Compliance with the National Environmental Policy Act (NEPA) - As outlined in 7 CFR Part 3407 (the CSREES regulations implementing NEPA), the environmental data or documentation for any proposed project is to be provided to CSREES in order to assist CSREES in carrying out its responsibilities under NEPA. In some cases, however, the preparation of environmental data may not be required. Certain categories of actions are excluded from the requirements of NEPA.

In order for CSREES to determine whether any further action is needed with respect to NEPA (e.g., preparation of an environmental assessment (EA) or environmental impact statement (EIS)), pertinent information regarding the possible environmental impacts of a proposed project is necessary; therefore, the National Environmental Policy Act Exclusions Form (Form CSREES-2006) provided must be included in the proposal indicating whether the applicant is of the opinion that the project falls within one or more of the categorical exclusions. Form CSREES-2006 should be included at the end of the proposal.

Even though a project may fall within the categorical exclusions, CSREES may determine that an EA or an EIS is necessary for an activity, if substantial controversy on environmental grounds exists or if other extraordinary conditions or circumstances are present which may cause such activity to have a significant environmental effect.

6.0 SUBMISSION OF PROPOSALS

6.1 Deadlines for Proposals

All phase I proposals must be received at USDA on or by August 30, 2001. Proposals not received by this date will not be considered for funding, with the following exceptions. Proposals received after August 30, 2001, will be accepted provided they are postmarked before or on (1) August 29, 2001, if sent by overnight courier; (2) August 28, 2001, if sent by priority mail; (3) or August 23, 2001, if sent by regular first class mail.

All phase II proposals must be received at USDA on or by **February 7, 2002.** Proposals not received by this date will not be considered for funding, with the following exceptions. Proposals received after February 7, 2002, will be accepted provided they are postmarked before or on (1) February 6, 2002, if sent by overnight courier; (2) February 5, 2002, if sent by priority mail; (3) or January 31, 2002, if sent by regular first class mail.

Only those small businesses previously receiving phase I awards in either fiscal years 2000 or 2001 are eligible to submit phase II proposals in fiscal year 2002. The SBIR Program Director will send a letter to all eligible phase I awardees requesting phase II proposals.

For the convenience of all potential proposers, the following schedule is provided:

Phase I

Delivery receipt date Period of research performance Final Report due at USDA on or by August 30, 2001 May 15, 2002 - November 30, 2002 December 31, 2002

Phase II

Delivery receipt date on or by **February 7, 2002**Beginning period of research performance approximately **September 1, 2002**

6.2 Number of Copies

Proposers under both phase I and phase II are requested to submit an **original and 15 copies** of all proposals. These proposals must contain all of the information, **arranged in the same order**, as that outlined in section 3.0.

6.3 Address

Proposals, whether phase I or phase II, must be submitted to one of the following addresses:

The address for hand-delivered proposals or proposals submitted using an express mail or overnight courier service is:

SBIR Program
Proposal Services Unit/CSREES/USDA
Room 1307, Waterfront Centre
800 9th Street, S.W.
Washington, D.C. 20024
Telephone: (202) 401-5048

The address for proposals sent via the **U.S. Postal Service** is: SBIR Program c/o Proposal Services Unit/CSREES/USDA STOP 2245
1400 Independence Avenue, S.W. Washington, D.C. 20250-2245

6.4 Acknowledgment of Proposals

The receipt of proposals will be acknowledged by e-mail. Therefore, applicants are encouraged to provide e-mail addresses, where designated, on the Proposal Cover Sheet, Form CSREES-667. If the applicant's e-mail address is not indicated, CSREES will acknowledge receipt of the proposal by letter. If the applicant does not receive an acknowledgment within 60 days of the submission deadline, please contact the Program Director (see subsection 1.1 for address, telephone, and facsimile numbers).

6.5 Bindings

Do not use special bindings or covers on proposals submitted in response to this program solicitation. Staple all pages together securely in the upper left-hand corner of each copy of each proposal.

6.6 Packaging

If possible, the original and all copies of each proposal should be mailed in one package. Due to the volume of proposals received, applications submitted in several packages are very difficult to identify and track. If it becomes necessary to mail copies of a proposal in more than one package, the number

of packages should be marked on the outside of each. It is important that all packages be mailed at the same time.

6.7 Questions Pertaining to the USDA SBIR Program or to this Solicitation

Written or verbal questions of a general nature about the USDA SBIR program, as well as general questions pertaining to this solicitation (but **not** pertaining to requests for additional copies of the solicitation), should be directed to Dr. Charles F. Cleland, Director, SBIR Program (see subsection 1.1 for address, telephone, and facsimile numbers).

6.8 Requests for Additional Copies of this Solicitation

Additional copies of this solicitation may be ordered by writing to the address shown in subsection 6.3 or by calling (202) 401-5048.

These materials may also be requested via Internet by sending a message with your name, mailing address (not e-mail) and phone number to psb@reeusda.gov which states that you want a copy of the application materials for the Fiscal Year 2002 Small Business Innovation Research Grants Program. The materials will then be mailed to you (not e-mailed) as quickly as possible.

6.9 Information on Proposal Status

It is anticipated that the evaluation of **phase I** proposals will require approximately 6 months from August 30, 2001, and no information on proposal status will be available until final selections have been made. Both successful and unsuccessful proposers will be notified of final award decisions within approximately 6 months.

Evaluation of **phase II** proposals will require approximately four months from February 7, 2002. Again, proposers are discouraged from making inquiries regarding the status of their proposals. All proposing organizations will be notified of final award decisions within approximately 4 months.

7.0 SCIENTIFIC AND TECHNICAL INFORMATION SOURCES

Listed below are some of the sources that can provide technology search and document services which may be useful in preparing SBIR proposals. They can be contacted directly for service and cost information.

National Agricultural Library Service Desk U.S. Department of Agriculture 10301 Baltimore Avenue Beltsville, Maryland 20705-2351 (301) 504-5755

National Technology Transfer Center Wheeling Jesuit University 316 Washington Avenue Wheeling, West Virginia 26003 (304) 243-2455 or (800) 678-6882 National Technical Information Service 5285 Port Royal Road Springfield, Virginia 22161 (800) 553-6847

Center for Technology Commercialization 1400 Computer Drive Westborough, Massachusetts 01581-5043 (508) 870-0042

Great Lakes Industrial Technology Center 25000 Great Northern Corporate Center, Suite 260 Cleveland, Ohio 44070 (440) 734-0094

Mid-Atlantic Technology Applications Center University of Pittsburgh 3400 Forbes Avenue, Eureka Bldg., 5th Floor Pittsburgh, Pennsylvania 15260 (412) 383-2500

Mid Continent Technology Transfer Center Texas Engineering Extension Service The Texas A&M University System College Station, Texas 77840 (979) 845-8762

NERAC, Inc. One Technology Drive Tolland, Connecticut 06084-3900 (860) 872-7000

Rural Enterprises, Inc. 2912 Enterprise Blvd. Durant, Oklahoma 74702 (580) 924-5094

Sciencewise 300 Professional Drive, Suite 200 Gaithersburg, Maryland 20879 (301) 975-0103

Southern Technology Applications Center College of Engineering University of Florida 1900 SW 34th Street Gainesville, Florida 32608 (352) 294-7822

8.0 RESEARCH TOPIC DESCRIPTIONS

SBIR proposals are solicited from the full range of topic areas that follow. Specific subtopics are listed only as **examples** of advanced applications or basic research of interest to USDA and are **not to be interpreted as exclusive.** It is USDA's intention to provide sufficient flexibility to obtain the greatest degree of creativity and innovation possible, consistent with overall SBIR and USDA program objectives. USDA reserves the right to shift proposals to a more appropriate topic when necessary for adequate review.

8.1 Forests and Related Resources

(A) Scope of Research

The objective of this topic is to develop environmentally sound techniques to increase productivity of forest land and to increase the utilization of materials and resources from forest lands. These areas deal with (l) increasing growth and yield through improving planting stock, reducing pathogens and insects, improving the soil or reducing harvesting impacts, and developing means to ensure survival of newly planted trees; (2) increasing the utility of the material grown in the forest through improving lumber yield from trees, utilizing greater percentages of trees, and using residues from forest and wood manufacturing systems; (3) reducing ecological damage from forest operations; (4) reducing the risk of and controlling wildfire on forest land; and (5) developing new products or technologies to increase the use of wood.

(B) Suggested Subtopics

Appropriate subtopics for innovative research proposals from small business concerns include, but are not limited to, the following:

(1) Growth and yield

Improving growing stock, tissue culture, genetic manipulation or vegetative reproduction of forest trees and other means of increasing the regenerative abilities of forests.

Reducing pathogens and insects - The volume of material lost to disease and insects exceeds that used for lumber and associated wood products. Subjects applicable here are those that reduce the impact of destructive agents.

Improving soil or reducing harvesting impacts - The fixing of nitrogen by symbiotic agents through genetic manipulation or by mycorrhizae to increase forest productivity through nitrogen enrichment of forest soils; research to reduce soil erosion, compaction, or other alterations caused by harvesting or forest operations (that is, physical improvement of forest soils).

Developing systems to increase the survival of newly planted trees through mechanical, physical, or chemical means that are environmentally safe.

(2) Increasing the utility of forest-grown material

Improving lumber yield or other means of increasing the volume and worth of wood from individual trees.

Utilizing a greater percentage of the tree through improved or new techniques of veneering or comminution so that new or improved reconstituted products can be made.

- **(3) Reducing ecological damage by forest operations** Research which provides for the economic recovery of resources from forests while raising potential productivity and reducing impacts to the ecological structure of the area of operation.
- **(4) Developing technology that facilitates the control of wildfires on forest lands** systems for detecting and managing wildfires; systems for reducing fuel loads in forests; tools and equipment for improving the efficacy and safety of fire fighters on the ground and in the air; communication and navigation systems for improving the coordination of fire management activities.
- **(5) Developing new products or technologies to increase the use of wood** Products using wood as a basic component of systems to replace or compete with construction materials or techniques.

8.2 Plant Production and Protection

(A) Scope of Research

The objective of this topic is to examine means of enhancing crop production by reducing the impact of harmful agents, developing effective crop systems that are economically and environmentally sound, enhancing the impact of new methods of plant manipulation, and developing new crop plants and new uses for existing crops. Proposals submitted to this topic will be divided between two review panels, one dealing with biological approaches, and the other dealing with non-biological approaches.

(B) Suggested Subtopics

Examples of research activities that would be appropriate for small business concerns include, but are not limited to, the following:

- (1) Plant production Improving the efficiency of crop production by utilizing innovative methods such as those of biotechnology, molecular biology, genomics and tissue culture and embryogenesis; developing improved methods and equipment for planting, growing and harvesting crop plants; and developing new crop plants (both terrestrial and aquatic) as sources of food, fiber or industrial products.
- **(2) Plant protection** Reducing the impact of plant pathogens and insect pests on crop plants; increasing plant resistance to plant pathogens and insect pests; and developing efficient and environmentally safe pesticide and herbicide usage equipment.
- **(3) Energy conservation** Developing crop management systems, farm structures, and waste utilization for efficient use of energy.

8.3 Animal Production and Protection

(A) Scope of Research

The overall objective of this topic area is to develop knowledge that will enable producers of food animals to increase production efficiency and to assure a reliable, safe supply of animal protein and other animal products while conserving resources and reducing costs of production. Some examples of the areas of research to be supported are: clarification of the nutritional requirements of food animals for improved growth and feed efficiency; determination of hormonal and cellular mechanisms which control reproduction and multiple births; clarification of genetic processes that result in food animals

with superior characteristics; improved methods of disposal of animal wastes; and diagnosis, treatment and control of food animal diseases, parasitisms and other animal health hazards.

(B) Suggested Subtopics

Appropriate subtopics for innovative research proposals from small business concerns include, but are not limited to, the following:

(1) Animal Production

- (a) Animal nutrition and digestive physiology Research directed at understanding the interrelationships between alimentary microbial ecosystems, digestive processes, and the host animal, and providing nutritional characterization of feedstuffs and integrated nutrient management to enhance production efficiency.
- **(b) Animal reproduction** Research on the control of estrus, ovulation and fertilization; enhanced embryo survival and development; enhanced parturition and perinatal survival; and advances in embryo technology such as sex control, twinning, frozen embryos and cloning.
- **(c) Animal genetics and breeding** Studies aimed at germplasm improvement in food animals that will provide animals with superior characteristics in areas such as reproduction, growth and development, lactation and egg production, lean-to-fat ratios, and disease resistance. These studies may employ innovative application of traditional methods, or incorporate novel biotechnological approaches, including, but not limited to cell and tissue culture, molecular biology, and genomics.
- **(d) Livestock management systems** Development of systems or processes that can be applied to food animal production enterprises that will provide greater efficiency in the production process and reduce the impact of these operations on the environment.

(2) Animal Protection

- **(a) Diagnostic tests** Development of diagnostic tests for specific diseases and agricultural chemicals which pose a health hazard to food animals and a residue problem in animal food products.
- **(b) Therapeutic methods** Treatment or treatment methods for acute or chronic health problems of food animals caused by specific infectious or non-infectious agents, parasitisms, chemicals and toxic agents, poisonous plants, injuries and other animal health hazards.
- **(c) Immunization methods** Vaccines, bacterins or other methods to establish or enhance resistance of food animals to infectious diseases and parasitisms.
- **(d) Pest control strategies** Development of alternative pest control or eradication methods so as to limit the use of and dependence on biotoxic substances. Such alternatives may include biological methods, sterile male techniques, artificial pheromones, and similar strategies.
- **(e) Preventive management** Development of management methods designed to protect food animals against health hazards.
- **(f) Animal health costs** Development of methodologies to accurately assess economic losses to animal health hazards and to measure economic benefits of alternative methods of prevention and control.

8.4 Air, Water, and Soils

(A) Scope of Research

The objective of this research area is to develop technologies for conserving and protecting air, water, and soil resources while sustaining agricultural productivity. This involves developing means to effectively control resources to increase farm and forest productivity and the manufacture of resulting commodities.

(B) Suggested Subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

- (1) Research to reduce losses of soil and soil nutrients or alteration of the physical nature of soil; technologies that enhance soil properties while restricting environmental perturbation.
- (2) Studies involving reduction of wind-caused erosion of soil; abatement of air pollution stemming from agricultural and forestry enterprises; utilization of air components for agricultural purposes.
- (3) Development of improved methodologies for conserving water resources, restoring water quality, and determining proper irrigation usage to meet current and future agricultural and forestry needs.

8.5 Food Science and Nutrition

(A) Scope of Research

The objectives of food science and nutrition research programs are to develop new knowledge and a better understanding of the characteristics of the foods we eat and their nutritional impact; to apply new knowledge to improve our foods and our diets; and to systematically apply new knowledge to the production of useful new food products, processes, materials and systems, including application of nutritional information to consumer foods and food service systems.

(B) Suggested Subtopics

Research opportunities are many and varied. Areas appropriate for innovative research proposals from small business concerns might include, but not necessarily be limited to, the following:

- (1) Chemistry and biochemistry Novel or rapid assay or bioassay techniques for food constituents, nutrients, properties, or interactions. Quality control techniques or rapid methods for in-plant nutrient analyses are needed.
- **(2) Microbiology and toxicology** Rapid, efficient methods for determining presence of organisms and detecting the development of toxic metabolites, including systems for determining shelf-life and "pull date" of food items, are needed.
- **(3) Processing** Methods for automation of processes and tests; rapid analyses and cataloging of physical properties; processing parameters; package design; design of material, energy- and water-efficient processes for small industries; development of specialty products or processes; on-line monitoring and control of nutrient, ingredient, or additive levels.
- **(4) Economics and statistics** Improved sampling procedures for dry mixes; cost/benefit analyses; and modeling systems, including distribution, warehousing and retailing systems.

(5) Nutrition Education - Developing and using information technology to convey important nutritional information and awareness to the public.

8.6 Rural and Community Development

(A) Scope of Research

The objectives of this research area are to foster, promote, or improve the well-being of rural Americans. This program supports research that will result in commercial products or services that are focused on issues and problems related to the economic development and social enhancement of rural areas, small towns, rural people, rural organizations, and rural institutions. Proposals submitted to this area should not concentrate primarily on the development of new technology, but rather on applying new or existing technology to address important issues and/or solving significant problems of importance to rural America. Proposals that involve development of new technology should explicitly discuss the specific rural problem or opportunity that will be examined, and how this technology will successfully address the problem or opportunity. The proposals do not need to be centered on agriculture, per se, but may be focused on any area (e.g., information systems, education, health care) that has the potential of providing significant benefits to rural Americans. Most of the competitive proposals submitted to this topic should include a market feasibility study as one of the research objectives.

(B) Suggested subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

- (1) Application of social science principles to processes that promote or foster **development of income or employment opportunities in** rural areas. Topics in this area may include products or services that enhance availability and capabilities of entrepreneurs, promote innovative ways to organize production systems to increase efficiencies and profitability of rural firms, or stimulate the development of new agricultural enterprises to improve farm profitability.
- (2) Studies that will result in **improvements in service delivery by local governments and public institutions** in rural areas. Areas of interest include educational programs that address the specific needs of people in rural areas, new housing designs that enhance the availability, quality and affordability of rural housing, improved health care delivery systems for different segments of the rural population, and information and managerial systems that improve the efficiency and effectiveness of local governments.
- **(3)** Commercialization of technologies that will provide the foundation for **employment and revenue generating opportunities** in rural areas. These technologies could be farm-based to promote more efficient and profitable farming systems or to enhance farm safety, or they could be focused on the general needs of rural people in areas such as transportation, telecommunications, waste disposal, and resource management.

8.7 Aquaculture

(A) Scope of Research

The objective of this research area is to enhance the knowledge and technology base necessary for the continued growth of the domestic aquaculture industry as a form of production agriculture. Emphasis is placed on research leading to improved production efficiency and increased competitiveness of private sector aquaculture in the United States. Studies on commercially important (or potentially important) species of fish, shellfish and plants, from both freshwater and marine environments, can be addressed.

(B) Suggested Subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to the following:

- (1) Reproductive Efficiency Novel or innovative approaches to improve reproductive efficiency in aquaculture including: greater control of maturation, ovulation, and fertilization; improved gamete and embryo storage; improved larval rearing techniques; enhanced reproductive performance of broodstock; and methods to control sex determination.
- (2) Genetic Improvement Novel or innovative approaches to improve production efficiency through genetic improvement of aquacultural stocks including: genetic mechanisms of sex determination; genetic basis for inheritance of commercially important traits such as growth, cold tolerance and pathogen susceptibility; identification of major genes affecting performance; application of molecular biology and genomics and the integration of this technology into breeding programs; basic gene structure and expression in aquatic species; performance evaluation of aquacultural stocks and utilization of crossbreeding and hybridization.
- (3) Integrated Aquatic Animal Health Management Novel or innovative approaches to reducing acute and chronic losses related to aquatic animal health in aquaculture production systems through an integrated holistic approach including: physiological stress related to the quality of the aquatic production system; genetic, environmental and nutritional components of aquatic health management; control of predation in aquaculture production systems; development of new vaccines or immunization procedures to enhance resistance to infectious diseases and parasitisms; development of diagnostic tests for specific diseases that pose a health hazard; and development of improved treatment methods for acute or chronic health problems caused by specific infectious or non-infectious agents, parasitisms, injuries, and chemical and toxic agents.
- (4) Improved Production Systems and Management Strategies Novel or innovative approaches to improving existing or alternative production system design and management strategies including: development of biological, engineering and economic design criteria and models; enhancement of water quality in existing production systems through aeration, flow patterns, etc.; characterization, handling and treatment of effluent from aquacultural production systems; improved harvesting methods and strategies.

8.8 Industrial Applications

(A) Scope of Research

The objective of this research area is to develop new or improved technologies that will lead to **increased production of industrial products from agricultural materials.** This research will lead to new opportunities to diversify agriculture and enhance agriculture's role as a reliable supplier of raw

materials to industry. Appropriate research areas are: development of new crops that have the potential of producing raw materials that can be converted into useful industrial products; development of procedures for enhanced recovery of critical raw materials from agricultural commodities; development of improved technology for converting agriculturally derived raw materials into useful industrial products; and development of industrial products derived from agricultural materials to make them more effective and/or more cost competitive with non-agriculturally derived industrial products.

(B) Suggested Subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

- (1) Oils and Lubricants Development of new agricultural sources of industrial oils and waxes for use as lubricants, cosmetics, soaps and detergents, plastics, paints, and many types of coatings.
- (2) Natural Rubber Improved technology for the production of resin and improvement in the quality of the natural rubber, and research into new applications for bagasse and other co-products.
- **(3) Fuels** New and improved technology for conversion of agriculturally important biomass material into alcohol and other products to be used as fuel additives and fuel substitutes.
- **(4) Chemicals from Starch** Development of new products such as absorbants and specialty chemicals from corn and other starchy crops.
- **(5) Fibers** New and improved technology for production of fiber from kenaf and other promising new fiber crops.

8.9 Marketing and Trade

(A) Scope of Research

The objective of this research area is to identify an array of innovative marketing strategies to increase sales of agricultural, forestry, and aquacultural products (raw commodities, plus processed, value-added food, feed, and industrial products derived from these commodities), both domestically and abroad. This research will assess and evaluate the type, size, and location of market opportunities for specific U.S. products or categories of products; develop specific strategies to gain entry into these markets or expand sales in current markets for specific products or categories of products; identify barriers to trade and develop specific strategies that neutralize these barriers; develop advanced information systems that provide more complete, relevant and timely information relative to temporal marketing opportunities; and develop integrated management systems that would permit maximum efficiencies in assembling, handling, processing, packaging, transporting, and shipping products. Where appropriate, foreign travel may be approved provided justification is adequately documented in the proposal.

(B) Suggested Subtopics

Examples of appropriate subtopics for research proposals from small businesses include, but are not limited to, the following:

(1) Development of Marketing Systems - Develop post harvest, integrated management systems that take raw, partially processed, or fully processed products and improves the efficiency in assembling, packing, processing, and shipping products to "niche," regional, national, and international markets. Included in this subtopic would be the development of methods that define strategies to: (a) better

integrate collection/assembly systems, (b) minimize seasonal variations in production and processing levels; (c) improve product characteristics through the use of such systems; and, (d) design more efficient packaging, storing, and transportation systems, including intermodal systems.

- (2) Development of Innovative Real-Time/Near Real-Time Information Systems Develop current and projected economic information on product sales, potential demand, prices, quality standards and specifications, varietal and packaging preferences, and relevant time periods in either real-time, or near-real-time to enable firms to respond more rapidly to national and international marketing opportunities. Also involved in this subtopic would be innovative information products that can inform businesses of the availability, features, and economics of new technologies and innovations, preferably using electronic media with interactive features.
- (3) Assessments and specification of marketing opportunities Identify new national and international markets, or the potential for increasing sales of U.S. forestry, agricultural, and aquacultural products in these markets. Quantify to the extent possible, market characteristics determining demand, product demand, and market structure; other changes relative to consumption patterns at home and abroad; shifts in retail and wholesale marketing; shifts in food manufacturing; and other changes that are relevant to successful marketing.

9.0 SUBMISSION FORMS AND CERTIFICATIONS

(Note: The following forms may need reformatting depending on your software or printer. Each form should be formatted to fit on to one page.)

Form CSREES-667 - Proposal Cover Sheet

Form CSREES-668 - Project Summary

Form CSREES-2004 - Budget

Form CSREES-2008 - Assurance Statement(s)

Form CSREES-2006 - National Environmental Policy Act Exclusions Form

UNITED STATES DEPARTMENT OF AGRICULTURE SMALL BUSINESS INNOVATION RESEARCH

SOLICITATION NO. USDA / 02-1

PHASE I AND PHASE II PROPOSAL COVER SHEET

| OMB Approved 0524-002 | 25 |
|-----------------------|----|
|-----------------------|----|

Proposal No. (for USDA use only) Date Received

| SUBMITTED | Firm: | | | | | |
|--|-----------------------|---|-----------------------------------|------------------------------------|-------------|----|
| | Mailing Address: | | | | | |
| | | | | | | |
| Project Title: | | | | | | |
| Topic No. and Area (check appr 9 8.1 Forests and Related Res 9 8.2 Plant Production and Pro 9 8.3 Animal Production and I | ources otection | .0) 9 8.4 Air, Water, and Soils 9 8.5 Food Science and Nu 9 8.6 Rural and Community | | 9 8.7 Aqı 9 8.8 Ind 9 8.9 Ma | ustrial App | |
| Amount Requested: (\$) | | Proposed Duration (Mos.): | Congressional District No. | : | YES | NO |
| The above concern c solicitation (See subsect | | the first two criteria of a small busin | ness concern as stated in thi | İs | | |
| | | es as a socially and economically dis 4). (For statistical purposes only). | advantaged small business a | as | | |
| 3. The above concern c subsection 2.5). (For st | | es as a women-owned small busines ly). | s as defined in this solicitation | on (See | | |
| | | cipal Investigator's primary employmers and during the conduct of the p | | | | |
| 5. The above concern of will be performed by this | | f two-thirds of the research (phase I) n 2.2(D)). | or one-half the research (pl | hase II) | | |
| name, address, and telep | phone number of the | se the title and technical abstract pa corporate official of your firm, if you contacting you for future information | ur proposal does not result in | | | |
| 7. Do you plan to send, acronym(s); e.g., DOE, N | | nis proposal or a similar one to any o | ther Federal agency? If yes, | , give | | |
| 8. Is the organization de information). | elinquent on any Fede | eral Debt? (See subsection 5.11). (| lf yes, attach explanatory | | | |
| 9. Will the work in this complete Form CSREES- | | ombinant DNA, living vertebrate anin | nals, or human subjects? (If | yes, | | |
| 10. Is this proposal a road. 3.3(D)). If yes, list the page 1. | | posal submitted earlier to the USDA | SBIR Program (See subsecti | ion | | |
| | | providing the required certifications set forth in 7 CFR the Certifications and Instructions included in this solic st of its knowledge and accepts as to any grant award ne of the award. *Submission of the Social Security N | | | | |

| PRINCIPAL | . INVESTIGATOR | AUTHORIZED ORGA | ANIZATIONAL OFFICIAL |
|-----------------------------------|----------------|-----------------|----------------------|
| Name and Social Security Number*: | | Name: | |
| Title: | | Title: | |
| Address: | E-mail: | Address: | |
| Telephone No.: | Fax No.: | Telephone No.: | Fax No.: |
| Signature: | Date: | Signature: | Date: |

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0524-0025. The time required to complete this information collection is estimated to average 1.4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

PROPRIETARY NOTICE (IF APPLICABLE, SEE SUBSECTION 5.4)

U.S. DEPARTMENT OF AGRICULTURE

OMB Approved 0524-0025

SMALL BUSINESS INNOVATION RESEARCH PHASE I AND PHASE II PROJECT SUMMARY*

| FOR USDA USE ONLY | | | | | |
|--|-------------------------------|---------------------------------------|------------|--|--|
| Program Office: | Solicitation No.: | Proposal No.: | Topic No.: | | |
| | | | | | |
| | TO BE COM | MPLETED BY PROPOSER | | | |
| Name and Address of Firm: | Nan | me and Title of Principal Investigato | r(s): | | |
| | | | | | |
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| Title of Draiget (00 character mayimuu | | | | | |
| Title of Project (80-character maximur | n): | | | | |
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| Technical Abstract (200-word limit): | | | | | |
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| Anticipated Results/Potential Commer | cial Applications of Research | າ (100-word limit): | | | |
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| Keywords to Identify Technology/Reso | earch Thrust/Commercial Ap | plication (8-word maximum) | | | |
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According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0524-0025. The time required to complete this information collection is estimated to average 3.75 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

C The Project Summary must be suitable for publication by USDA in the event of an award. Do not include proprietary information on this page.

UNITED STATES DEPARTMENT OF AGRICULTURE COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE

OMB Approved 0524-0039 Expires 03/31/2004

RUDGET

| ODC ANIZATION AND ADDRESS | | | DUDGE | I | | | |
|--|---------------|---------------|-----------|--------------------------|-----------------------------|------------------------------------|---------------------------------------|
| ORGANIZATION AND ADDRESS | | | | USDA AWARD NO. DURATION | DURATION | Non-Federal | Non-federal Cost- |
| | | | | PROPOSED MONTHS: | PROPOSED MONTHS: | Proposed Cost- Sharing/Matching | Sharing/Matching Funds Approved by |
| PROJECT DIRECTOR(S) | | | | Funds Requested | Funds Approved | Funds (If required) | CSREES (If Different) |
| | | | | by Proposer | by CSREES (If different) | (1,) | |
| A. Salaries and Wages | | UNDED WORK | 1 | | | | |
| 1. No. Of Senior Personnel | Calendar | Academic | Summer | | | | |
| a (Co)-PD(s) | | | | \$ | \$ | \$ | \$ |
| No. of Other Personnel (Non-Faculty) | | | | | | | |
| a Research Associates/Postdoctorates | | | | | | | |
| c. Paraprofessionals | | | | | | | |
| d Graduate Students | | | | | | | |
| e. Prebaccalaureate Students | | | | | | | |
| f. Secretarial-Clerical | | | | | | | |
| g Technical, Shop and Other | | | | | | | |
| Total Salaries and Wages | | | | | | | |
| B. Fringe Benefits (If charged as Direct Costs) | | | | | | | |
| C. Total Salaries, Wages, and Fringe Benefits (| Δ nlus R) | | 6 | | | | |
| D. Nonexpendable Equipment (Attach supportin | | | | | | | |
| amounts for each item.) | ig data. Lis | t items and t | uonai | | | | |
| E. Materials and Supplies | | | | | | | |
| F. Travel | | | | | | | |
| G. Publication Costs/Page Charges | | | | | | | |
| H. Computer (ADPE) Costs | | | | | | | |
| All Other Direct Costs (In budget narrative, I provide supporting data for each item.) | ist items and | d dollar amo | unts, and | | | | |
| J. Total Direct Costs (C through I) | | | 6 | | | | |
| K. F&A/Indirect Costs (If applicable, specify rat campus activity. Where both are involved, ic on/off campus bases.) | | | | | | | |
| L. Total Direct and F&A/Indirect Costs (J plus I | K) | | 6 | | | | |
| M. Other | | | 6 | | | | |
| N. Total Amount of This Request | | | 6 | \$ | \$ | \$ | \$ |
| O. Carryover (If Applicable) | . Federal F | unds: \$ | | Non-Federal fu | nds: \$ | Total \$ | |
| P. Cost-Sharing/Matching (Breakdown of total | amounts sho | own on line | N) | | | | |
| Cash (both Applicant and Third Party) | | | | | 6 | \$ | \$ |
| Non-Cash Contributions (both Applicant a | nd Third Par | rty) | | | 6 | \$ | \$ |
| NAME AND TITLE (Type | e or print) | | | SIGNATURE | (required for revised | budget only) | DATE |
| Project Director | | | | | | | |
| Authorized Organizational Representative | | | | | | | |
| Signature (for optional use) | | | | | | | |

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0524-0039. The time required to complete this information collection is estimated to average 1.00 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

UNITED STATES DEPARTMENT OF AGRICULTURE COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE

ASSURANCE STATEMENT(S) - FOR RESEARCH PROJECTS

| STATEMENT OF POLICY - Institutions receiving CSREES funding for research are responsible for protecting human subjects, providing humane treatment of animals, and monitoring use of recombinant DNA. To provide for the adequate discharge of this responsibility, CSREES policy requires an assurance by the institution's Authorized Organizational | | Representative (AOR) that appropriate committees in each institution have carried out the initial reviews of protocol and will conduct continuing reviews of supported projects. CSREES also requires AOR certification by citing a timely date that an appropriate committee issued an approval or exemption. | | | | |
|---|---|--|--|--|--|--|
| NOTE: Check appropriate statements, supplying additional information when necessar | y. | | | | | |
| 1. INSTITUTION | | 2. CSREES PROJECT NUMBER OR AWARD NUMBER (if known) | | | | |
| | 3. PR | OJECT DIRECTOR(S) | | | | |
| 4. TITLE OF PROJECT | | | | | | |
| A. BIOSAFETY OF RECOMBINANT DNA 9 Project does not involve recombinant DNA. 9 Project involves recombinant DNA and was either approved (Biosafety Committee (IBC) on | nplying w | ith both the intent and procedures of | | | | |
| B. CARE AND USE OF ANIMALS 9 Project does not involve vertebrate animals. 9 Project involves vertebrate animals and was approved by the (Date). | Institutior | al Animal Care and Use Committee | (IACUC) on | | | |
| This performing organization agrees to assume primary responsibility for con 1996, as amended, and the regulations promulgated thereunder by the Secretar animals housed under farm conditions, the institution shall adhere to the pragricultural Research and Teaching, Federation of Animal Science Societies, | ry of Agri inciples s | culture in 9 CFR Parts 1, 2, 3, and 4. | In the case of domesticated farm | | | |
| C. PROTECTION OF HUMAN SUBJECTS 9 Project does not involve human subjects. 9 Project involves human subjects and 9 Was approved by the Institutional Review Board (IRB) of number; if not, a Single Project Assurance, if not, a Single Project Assurance, it is exempt based on exemption number 9 Specific plans involving human subjects depend upon coordinate or procedures. No human subjects will be involved in research. | ce is requi mpletion of earch until | red. of survey instruments, prior animal strapproved by the IRB and a revised F | udies, or development of material form CSREES-2008 is submitted. | | | |
| This performing organization agrees to assume primary responsibility for comp CFR Part 46, 1991, as amended, and USDA regulations set forth in 7 CFR 1c, under continuing review by an IRB. If the performing organization submits a protect subjects from risks is required. | , 1992. Al | nonexempt research involving huma | an subjects must be approved and | | | |
| SIGNATURE OF AUTHORIZED ORGANIZATIONAL REPRESENTATI | VE | TITLE | DATE | | | |

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0524-0039. The time required to complete this information collection is estimated to average .50 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

CSREES-2008 (12/02/00)

Instructions for Completing Assurance Statements and Certifications of Protection from Research Risks

STATEMENT OF POLICY - Institutions receiving CSREES funding for research are responsible for protecting human subjects, providing humane treatment of animals, and monitoring the use of recombinant DNA. To provide for the adequate discharge of this responsibility, CSREES policy requires an assurance by the institution's Authorized Organizational Representative (AOR) that appropriate committees in each institution have carried out the initial reviews of protocol and will conduct continuing reviews of supported projects. CSREES also requires AOR certification by citing a timely date that an appropriate committee issued an approval or exemption.

If a research proposal covers multiple projects in which experimental protocols vary, the AOR must provide documentation of certification, through multiple copies of Form CSREES-2008, by the appropriate committee(s) for each specific protocol utilized in the projects. Examples of multiple project/proposals may include large multi-faceted special grants, multi-institutional consortia, multi-state research projects and some large umbrella Hatch proposals.

Formula funded activities require a certification of action taken by appropriate committees, which necessitates inclusion of the date of the action; the designation of 'pending' is not an option. The designation of 'pending' may be inserted for other grant proposals in lieu of reporting a date of certification that an appropriate committee took action. However, a subsequent approval must be obtained, and a revised Form CSREES-2008 must be submitted before a final award can be made.

A. BIOSAFETY OF RECOMBINANT DNA

If the project involves the use of recombinant DNA molecules, the performing organization shall assume primary responsibility for complying with both the intent and procedures of the National Institutes of Health (NIH), DHHS, Guidelines for Research Involving Recombinant DNA Molecules, as revised:

http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

This responsibility includes:

- 1. Ensuring that a standing Institutional Biosafety Committee (IBC) is maintained in accordance with Part IV of the NIH Guidelines and also ensuring that the research plan is reviewed and approved by the IBC prior to commencing substantive work under the project. Actions by the IBC must be documented in Section A of the Form CSREES-2008.
- 2. Registering with the IBC all experiments involving recombinant DNA molecules conducted with funds provided under the project and complying with the containment requirements specified in Part III of the NIH Guidelines. Records of this research must be kept in a form that is available to CSREES upon request.

In addition, the funded recipient must report the following supplemental data to CSREES and to the reviewing IBC:

- a. New technical information relating to risks and safety procedures.
- b. Serious accidents or releases involving recombinant DNA.
- c. Serious illness of a laboratory worker which may be project related.
- d. Other safety problems.

The NIH Guide for Reporting the Occurrence of Serious Adverse Events is published at:

http://grants.nih.gov/grants/policy/recombinentdnaguidelines.htm

IBC review and approval must be documented in Section A of the Form CSREES-2008. The approval date should reflect a timely review. The approval date reported in section A of the Assurance Form 2008 should not be older than 36 months.

B. CARE AND USE OF ANIMALS

The responsibility for the humane care and treatment of vertebrate animals used in any research project supported with CSREES funds rests with the performing organization. If a project involves animals, except farm animals used for food and fiber research, the personnel identified with the project, and the endorsing officials of the recipient's organization must comply with the Animal Welfare Act (AWA). The AWA (7 USC, 2131-2156; Public Law 89-544, 1996, as amended) and the regulations promulgated thereunder by the Secretary of Agriculture (9 CFR Parts 1, 2, 3, and 4, and subsequent rules and regulations) pertain to the care, handling, and treatment of vertebrate animals held or used for research, teaching, or other activities supported by Federal awards:

http://www.nal.usda.gov/awic/legislat/awicregs.htm

In the case of laboratory animals used or intended for use in research, the institution shall adhere to the principles enunciated in the Guide for the Care and Use of Laboratory Animals, (ILAR, National Academy of Sciences); 1996:

http://www.nap.edu/readingroom/books/labrats/

and to the USDA regulations and standards issued under the public laws stated above. In case of a conflict between the guidelines, the higher standard shall be used.

When domesticated farm animals are used or intended for use in agricultural food and fiber production research, teaching or other activities and housed under farm conditions, the institution shall adhere to the principles stated in the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, 1999:

http://www.nal.usda.gov/awic/index.html

which is available from the Federation of Animal Science Societies, 1111 N Dunlap, Savoy, IL 61874.

Prior to commencing research activities with vertebrate animals, all protocols involving animals in CSREES funded projects must be approved by the Institutional Animal Care and Use Committee (IACUC):

http://grants.nih.gov/grants/oprr/library animal.htm

IACUC review and approval must be documented in Section B of the Form CSREES-2008. The approval date should reflect a timely review. The approval date reported in section B of the Assurance Form 2008 should not be older than 36 months.

C. PROTECTION OF HUMAN SUBJECTS

The performing organization is responsible for protecting the rights and welfare of any human subject involved in CSREES sponsored research and related activities. If a research project protocol involves the use of human subjects, the institution must agree to comply with the Department of Health and Human Services' (DHHS) regulations on the protection of human subjects:

http://ohrp.osophs.dhhs.gov/polasur.htm

as set forth in 45 CFR Part 46, 1991, as amended (formally adopted as "The Common Rule"), and USDA regulations set forth in 7 CFR 1c, 1992. If a research project protocol involves the use of human subjects, one and only one of the three options outlined under section C of Assurance Form 2008 must be checked.

All nonexempt research protocols involving human subjects must be approved and undergo continuing review by an Institutional Review Board (IRB). If the performing organization qualifies for Federalwide Assurance (FWA) status and has been approved by the Office for Human Research Protections (OHRP), DHHS, then report the assurance number along with the approval date. A list of IRBs with FWA status is available at:

http://ohrp.osophs.dhhs.gov/irbasur.htm

If the performing organization does not have MPA status, a Single Project Assurance (SPA) form may be obtained from OHRP, HHS at:

http://ohrp.osophs.dhhs.gov/humansubjects/assurance/spa.htm

and must be submitted. A SPA is a document to assure compliance and continuing review of the project being proposed, and it is limited in use and duration to this individual research activity. A SPA signed by the IRB Chairperson, AOR, and Project Director of the research project must be submitted. Also, provide additional information regarding the recruitment and selection of subjects, the proposed processes of informed consent and maintenance of confidentiality, and risk and benefit assessments for review by CSREES staff. An institution submitting a SPA may utilize its own IRB or the IRB of a neighboring institution.

The IRB approval date should reflect a timely review. The date reported in section C of the Assurance Form 2008 should not be older than twelve months, because the "Common Rule" requires annual review.

Research activities in which the only involvement of human subjects is in one or more of the following categories are exempt from IRB review:

- 1. Research conducted in established or commonly accepted educational settings.
- 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless information obtained is recorded in such a manner that human subjects can be identified, and any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk or be damaging.
- 3. Research not exempt in #2 may be exempt if, in the use of educational tests, the subjects are elected or appointed officials, or federal statutes require that confidentiality will be maintained.
- 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- 5. Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service programs.
- 6. Taste and food quality evaluation and consumer acceptance studies.

A complete explanation of these exemptions can be found at:

http://ohrp.osophs.dhhs.gov/humansubjects/guidance

A project may be funded but temporarily excused from IRB approval if specific protocols involving human subjects depend upon the development of survey instruments, procedures or materials, or completion of animal studies. However, human subjects may not be involved in research activities until IRB approval is obtained and a revised Form CSREES-2008 is submitted.

UNITED STATES DEPARTMENT OF AGRICULTURE COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE

OMB Approved 0524-0039 E Expires 03/31/2004

terms of changes in the environment

materials

in scope and intensity

Testing outside of the laboratory, such as in

small isolated field plots, which involves the

Routine renovation, rehabilitation, or revitalization of

installation of equipment, where such activity is limited

physical facilities, including the acquisition and

routine use of familiar chemicals or biological

National Environmental Policy Act Exclusions Form

| Project Director Name | Institution |
|-----------------------|-------------|
| | |
| Address | |
| | |

Under 7 CFR Part 3407 (CSREES's implementing regulations of the National Environmental Policy Act of 1969 (NEPA)), environmental data or documentation is required in order to assist CSREES in carrying out its responsibilities under NEPA, which includes determining whether the proposed activity requires the preparation of an environmental assessment or an environmental impact statement, or whether such activity can be excluded from this requirement on the basis of several categories. Therefore, it is necessary for the applicant to advise CSREES whether the proposed activity falls into one of the following Department of Agriculture or CSREES categorical exclusions, or whether the activity does not fall into one of these exclusions (in which case the preparation of an environmental assessment or an environmental impact statement may be required). Even though the applicant considers that a proposed project may or may not fall within a categorical exclusion, CSREES may determine that an environmental assessment or an environmental impact statement is necessary for a proposed project should substantial controversy on environmental grounds exist or if other extraordinary conditions or circumstances are present that may cause such activity to have a significant environmental effect.

Please Read All of the Following and Check All Which Apply

The proposed activity falls under the categorical exclusion(s) indicated below: **Department of Agriculture Categorical Exclusions CSREES Categorical Exclusions** (found at 7 CFR 1b.3 and restated at 7 CFR 3407.6 (found at 7 CFR 3407.6(a)(2)(i) through (ii)) (a)(1)(i) through (vii)) The following categories of CSREES actions are excluded [] (i) Policy development, planning and because they have been found to have limited scope and implementation which are related to routine intensity and to have no significant individual or cumulative activities such as personnel, organizational impacts on the quality of the human environment: changes, or similar administrative functions Activities that deal solely with the functions of [] The following categories of research programs or programs, such as program budget proposals, projects of limited size and magnitude or with only disbursements, and transfer or reprogramming short-term effects on the environment: of funds Research conducted within any laboratory, [] (iii) Inventories, research activities, and studies such greenhouse, or other contained facility where as resource inventories and routine data research practices and safeguards prevent collection when such actions are clearly limited environmental impacts Surveys, inventories, and similar studies that in context and intensity [] (iv) Educational and informational programs and have limited context and minimal intensity in

OF

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[] Proposed activity does not fall into one of the above categorical exclusions

(**NOTE**: If checked, please attach an explanation of the potential environmental impacts of the proposed activity. May require completion of an environmental assessment or an environmental impact statement.)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0524-0039. The time required to complete this information collection is estimated to average .25 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

activities

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(v) Civil and criminal law enforcement and

(vi) Activities that are advisory and consultative to

(vii) Activities related to trade representation and

market development activities abroad

other agencies and public and private entities,

such as legal counseling and representation

investigative activities

10.0 SAMPLE PROPOSAL FROM USDA SBIR SOLICITATION

A sample proposal, which resulted in a phase I award, and was submitted under the 1988 USDA SBIR Program Solicitation, may be downloaded from the following web site:

 $http://www.sbir.dsu.edu/home/proposal_preparation/sample_proposals/usda_sample2.htm$

The sample proposal is provided solely for general guidance. Note, the proposal format specified in this - the 2002 Solicitation - differs from that in earlier solicitations. The budget and current vitaes have been omitted and social security numbers have been deleted to protect confidentiality.